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“Overweight and obesity in relation to socio-economic status, tobacco smoking and plant food supplements usage”

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Que me enseñaron a buscar mi camino…

Al meu marit

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Que camina amb mi…

A mis hijos

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Que enriquecen cada paso…

EXECUTIVE SUMMARY

0. Rationale, aim and specific objectives

Rationale

Overweight and obesity prevalence rates have been increasing worldwide in the last few decades. This is also the case in the adult population from Catalonia, Spain.

Overweight and obesity are multi-factorial chronic diseases.

There are many strategies used by individuals for body weight control/loss. Although the diets of all sorts and physical activity are the most popular methods, also relevant ones are tobacco smoking (i.e. smokers are reluctant to give up smoking under the fear that they will gain body weight if they do so) and the usage of weight-loss plant food supplements (PFS).

This PhD thesis has been motivated by the following questions:

1. What are the prevalence rates of overweight and obesity in the Catalan adult population in two different points in time (1992-1993 and 2002-2003)?
2. Do socioeconomic (occupation and education) and sociodemographic (gender, age and population of residence size) factors relate to these prevalence rates?
3. Do popularly used weight control strategies such as tobacco smoking (in Catalonia) and PFS consumption (in six EU countries) relate to these prevalence rates?

Aim

This thesis aims firstly to respond to the questions posed on the rationale, with the intention to identify groups within the Catalan adult population who -according to their SES or their smoking habits- may be more vulnerable to excess body weight and fat. In addition, it aims to ascertain if consuming tobacco or PFS in weight control/loss has any relationship with overweight or obesity. Finally, it aims to contribute to the scientific literature related to overweight and obesity.

Specific objectives

The objectives of research chapter 1 are two: a) to evaluate the trends (1992–2003) of overweight and obesity prevalence rates in the adult population of Catalonia, Spain, and b) to explore the influence of some socio-economic (occupation and education) and socio-demographic (gender, age and population of residence size) variables on these prevalence trends.

Research chapter 2 has the objective of showing trends in the relationship between smoking history and overall overweight/obesity, and between smoking history and central fatness in an adult Catalan population.

Research chapter 3 has the objective to provide an overview of the characteristics and usage patterns of PFS consumers in six European countries. This chapter also contextualizes the work carried out in chapter 4.

Finally, research chapter 4's objectives are two: a) to provide an overview of the PFS botanical ingredients consumed for "body weight reasons" and by "dieters for overweight/obesity" in six European countries, and b) to explore the relationship between the consumption of these botanical ingredients and the self-reported BMI of their consumers.

1. Background

The background section is included to provide an overview of some relevant aspects on the two main research topics: 1.1) Obesity: excess body weight and adiposity and 1.2) Plant food supplements (PFS). Background 1.1 contextualizes research chapters 1 and 2, whereas background 1.2 contextualizes research chapters 3 and 4.

1.1 Obesity: excess body weight and adiposity – an overview

Obesity is characterised by altered body composition with increased adiposity. It is a multifactorial chronic disease whose origins involve environmental (related to sedentary habits, inadequate dietary habits and other lifestyle factors) and genetic factors (involving different polymorphisms).

The International Obesity Task Force (IOTF) and the World Health Organization (WHO) have declared obesity, as the epidemic of the 21st century due to the dimensions acquired within the last few decades, its impact on morbi-mortality, quality of life and related healthcare costs. The WHO recognizes the impact obesity has on the development of the most prevalent chronic diseases in our society: type 2 diabetes, cardiovascular diseases, musculoskeletal pathologies and an increasing number of certain cancers. Increased body weight also leads to the onset of depression, impaired cognitive functions and disorders related to body image, self-esteem, etc, resulting in impaired social interactions. Moreover, it generates important direct and indirect economic costs as well as significant increases in social and health services (medical visits, absenteeism, loss of autonomy, special needs, etc).

Prevention of excess body weight/adiposity is essential, requiring a multidisciplinary preventive approach.

Section 1.1 includes five subsections that provide an overview of different areas within the study of excess body weight and adiposity, including: the different techniques currently used to measure body weight and fatness (subsection 1.1.1); the body weight an fatness measures used in the present thesis i.e. Body Mass Index (BMI) and Waist Circumference (WC) (subsection 1.1.2); global, European and Spanish overweight and obesity prevalence rates and trends (subsection 1.1.3); the determinants of overweight and obesity (subsection 1.1.4); and the health effects of overweight and obesity (subsection 1.1.5).

1.2 Plant food supplements – relevant aspects

The popularity of botanical products is on the rise in Europe, with consumers using them to complement their diets or to maintain health, and products are taken in many different forms (e.g. teas, juices, herbal medicinal products, plant food supplements (PFS). However there is a scarcity of data on the usage of such products at European level.

Section 1.2 includes six subsections that provide information on relevant aspects related to the PFS topic for understanding the research carried out on PFS, including: a description of the PlantLIBRA EU project and the PlantLIBRA PFS Consumer Survey 2011-2012 (subsection 1.2.1); the concepts and definitions needed when collecting data on PFS consumption (subsection 1.2.2); an overview of the regulatory aspects related to PFS (subsection 1.2.3); an overwiew of PFS market data in EC Member States (subsection 1.2.4); a chronological overview of the weight management industry (subsection 1.2.5); and a general classification of botanical products used for body weight loss (subsection 1.2.6).

2. Research

My research has focused on the study of adult overweight and obesity in relation to the following environmental factors: 1) Socioeconomic (occupation and education) and sociodemographic (age, gender and population of residence size) factors, and 2) lifestyle factos (tobacco smoking and consumption of PFS). I have studied the relationship of overweight and obesity with occupation, education, age, gender population of residence size and smoking history in the Catalan adult population, using data from the two Catalan Nutrition Surveys (ENCATs 1992-1993 and 2002-2003) - two methodologically identical cross-sectional surveys. In addition, I have studied the relationship between overweight/obesity and the consumption of PFS in the adult population from 6 EU countries where the PlantLIBRA EU project's PFS Consumer Survey 2011-2012 was conducted. Each of the four research chapter contains its own *Introduction, Materials and Methods, Results* and *Discussion* sections. A summary of the objectives, methodology and results of each chapter is included in this executive summary. The conclusions and original contributions of each chapter are included in section 3 of the thesis.

2.1 Chapter 1 - Obesity and overweight trends in Catalonia, Spain (1992-2003): gender and socio-economic determinants

Objective: This study evaluates the trends of obesity and overweight prevalence rates in the adult population of Catalonia, Spain, and the influence of socio-economic variables on these prevalence trends.

Materials and methods: The analysis was based on data from two representative population-based cross-sectional surveys, i.e. the two Evaluations of Nutritional Status in Catalonia (ENCAT 1992–93 and ENCAT 2002–03). Trained interviewers obtained weights and heights by direct measurement in standardised conditions. Overweight and obesity were defined using BMI and WC, categorised according to 1998 WHO criteria. The overall samples consisted of 1015 men and 1233 women from ENCAT 1992–93, and 791 men and 924 women from ENCAT 2002–03, all aged 18-75 years.

Results: Mean BMI and mean WC were higher in males in 2002–03 as compared to 1992–93, while for females, mean BMI was lower (except for the youngest group), and mean WC was higher. In men, overall BMI overweight prevalence remained stable (from 44.1% to 43.7%), while obesity increased (from 9.9% to 16.6%); total WC overweight remained stable (from 21.7 to 23.8%), while WC obesity increased (from 13.1% to 24.4%). In women, overall BMI overweight and BMI obesity remained stable (from 29.1% to 30.1% and from 15.0% to 15.2% respectively); total WC overweight decreased (from 21.8% to 17.7%), while WC obesity increased (from 24.5% to 31.1%). The socio-economic and education variables had an influence on BMI and WC overweight and obesity rates mainly on females in both surveys and on the youngest men only in the 1992–93 survey.

2.2 Chapter 2 - Trends in the association between smoking history and general/central obesity in Catalonia (1992-2003), Spain

Objective: This study shows trends in the relationship between smoking history and both general overweight/obesity and central fatness in adults from the Mediterranean area of Catalonia, Spain.

Materials and methods: The ENCAT 1992-93 and ENCAT 2002-03 surveys were used: 482 men and 589 women from 1992-93 and 515 men and 613 women from 2002-03, all aged 25-60 years. Trained dieticians measured anthropometry (weight, height) and collected self-reported data on smoking habits, diet, lifestyle and SES. WHO's 2008 general overweight/obesity indicator (BMI>=25) was used among never, former, and current smokers; WHO's 2008 central fatness indicators used among never, former, and current smokers included the increased-risk-for-metabolic-disease waist circumference (IR WC - as a WC =94-<102 cm in men and =80-<88 cm in women) and the substantially-increased-risk-for-metabolic-disease WC (SIR WC - as a WC>=102 cm in men and >=88 cm in women). Multivariate-adjusted associations were estimated using simple logistic regression.

Results: By 2002-2003, male prevalence of both joint overweight/obesity and IR/SIR WC had increased; former-smokers had the highest overweight (57.2%) and SIR WC (28.2%), but never-smokers had the highest obesity (19.3%) and current-smokers the highest IR WC (30.7%). Disparities in female rates across smoking history groups were substantially diminished after ten years, due to the increased joint rates in former- and current-smokers, and the lower joint rates in never-smokers; highest overweight (32.2%) and IR WC (21%) were observed in former-smokers and highest obesity (16.5%) and SIR WC (33.2%) in never-smokers. After ten years, most associations between smoking history and general and central obesity had been strongly attenuated: only male current-heavy smoking remained associated with IR/SIR WC (two- instead of three-fold) and female current-moderate smokers were 0.57 times less likely to have an IR/SIR WC ($p<0.10$).

2.3 Chapter 3 - Usage of plant food supplements across six European countries: findings from the PlantLIBRA Consumer Survey

Objective: To provide an overview of the characteristics and usage patterns of plant food supplements (PFS) consumers in six European countries.

Materials and methods: This study was carried out within the PlantLIBRA project (FP7-EC funded project nº245199). Data on PFS usage were collected in a cross-sectional, retrospective survey of PFS consumers using a bespoke frequency of PFS usage questionnaire. The total sample consisted of 2359 adult PFS consumers from Finland, Germany, Italy, Romania, Spain and the United Kingdom. Descriptive analyses were conducted, with all data stratified by gender, age, and country. Absolute frequencies, percentages and 95% confidence intervals are reported.

Results: Overall, an estimated 18.8% of screened survey respondents used at least one PFS. Characteristics of PFS consumers included being older, well-educated, never having smoked and self-reporting health status as ‘‘good or very good’’. Across countries, 491 different botanicals were identified in the PFS products used, with *Ginkgo biloba* (ginkgo), *Oenothera biennis* (evening primrose) and *Cynara scolymus* (artichoke) being most frequently reported; the most popular dose forms were capsules and pills/tablets. Most consumers used one product and half of all users took single-botanical products. Some results varied across countries.

2.4 Chapter 4 - BMI overweight and obesity in relation to plant food supplement usage in six European countries: results from the PlantLIBRA PFS Consumer Survey 2011-2012

Objectives: This study aims to identify the botanicals of the plant food supplements (PFS) consumed for "body weight reasons" and by "dieters for overweight/obesity" in six European countries, as well as to explore the relationship between the consumption of these identified botanical ingredients and the self-reported BMI of their consumers.

Materials and methods: This study used data from the PlantLIBRA PFS Consumer Survey 2011-2012, a cross-sectional, retrospective survey of 2359 PFS consumers using a bespoke frequency-of-PFS-usage questionnaire. Analyses were performed in two consumer subsamples of 1) respondents taking the products for "body weight reasons", and 2) "dieters for overweight/obesity". Subsamples' country proportions are presented; consumed PFS botanicals by respondents of "body weight reasons", by "dieters for overweight/obesity" and by the "crosstabulation of the two groups" were identified. The relationship between the 5 most consumed botanicals and self-reported BMI in group 1 and 2 is explored by comparing BMI proportions of consumers vs. non-consumers of these botanicals (using χ^2 test, $p<0.05$ for significance). Comparisons were made using a) the "body weight reasons" sample (n=240) and the "dieters for overweight/obesity" sample (n=112), in which the top 5 consumed botanicals had actually been identified, and b) the total survey sample (N=2359) for increasing the power of the test.

Results: Of the total 2874 PFS products consumed, 252 (8.8%) were consumed for "body weight reasons" (by 240 PFS consumers). Of the total 2359 PFS consumers, 112 (4.8%) were "dieting for overweight/obesity". Spain is the country where "body weight reasons" and "dieting for overweight/obesity" were most popular. Artichoke was the most consumed botanical by a) respondents of "body weight reasons", by b) "dieters for overweight/obesity" and by c) the crosstabulation of the two. Considering the top 5 botanicals used by "body weight reasons" repondents, a significantly greater proportion of BMI>25 was observed among the consumers of PFS containing artichoke and green tea as compared to non-consumers (58.4% vs. 49.1% and 63.2% vs. 49.7% respectively); these results were obtained when using the total survey sample. Considering the top 5 botanicals used by "dieters for overweight/obesity", when the dieters sample was used, a significantly lower proportion of BMI>25 was observed among consumers of pineapple-containing PFS as compared to non-consumers (38.5% vs. 81.5%); however, when using the entire survey sample, the only significant difference was a greater proportion of BMI$\geq$25 among consumers of artichoke-containing PFS than among non-consumers (58.4% vs. 49.1%). The first three reasons for taking artichoke-containing products were "body weight" (in 79 products, of which

47 were consumed in Spain), “stomach/digestive function” (79 products, of which 37 were consumed in Germany) and “cholesterol” (32 products, 21 consumed in Germany).

3. Conclusions and original contributions

The results of the research carried out in this thesis have significant implications for public health. It has long been established that excess general and central body weight is an increasing public health problem, affecting more and more societies of all sorts, i.e. affluent, in transition and emerging ones. It is also well known that this public health problem is influenced by many factors, and that affected individuals seek all sorts of weight-control/loss strategies. Some of these factors and weight-control strategies have been addressed in this thesis.

Chapter 1: Ten-year trends indicated that Catalan males were getting bigger overall (BMI) and around the waistline (WC), while Catalan females only had bigger waistlines (WC). BMI male obesity prevalence had overtaken that of females. WC obesity continued to be more prevalent among females than males. In spite of the study limitations, findings for the Catalan adult male and female population would encourage urgent weight management actions to improve this collective’s health and to prevent co-morbidities, with special focus on the lower socio-economic and education level groups. This study was published in the journal *Public Health Nutrition* 2007 (impact factor (IF) in 2008: 2.123) (see Annex IVa), and presented as a poster at the VIII SENC Congress, Valencia, 22-25 October 2008.

Chapter 2: Although causality cannot be established, results suggest a positive association between heavy smoking (>20 cigarettes/day) and central fatness among men; the very small number of women who reported themselves to be heavy smokers limited the ability to examine associations between current heavy smoking and central obesity and to compare them with those observed in men. Nevertheless, no association between former smoking and general/central fatness was observed in the latest survey and these findings strengthen arguments for promoting smoking cessation to reduce morbidity and mortality associated with both smoking and obesity. This research chapter contributes to the global pool of evidence about this topic, because this analysis has never been done before in this population. The manuscript has been submitted to a scientific journal (see Annex IVb).

Chapter 3: This chapter presents the first results on the consumption of PFS in relation to the type of product consumed, the frequency of its consumption, and the botanical ingredients most frequently contained in these consumed products. Obtaining and handling all this information was a rather complex task, and conducting the survey in 6 EU countries simultaneously added in even more challenges. The survey is one of the main outcomes of the PlantLIBRA EU project and has represented a contribution to scientific research in this sector at the European level. Thanks to this project and survey, nowadays there are available data directly obtained from consumers in six EU countries that can be used in the future to carry out various types of research. In addition, a new methodology has been proposed and tested, which can be used and improved by future researchers of the topic for generating additional data. Thus, for example, incorporating measures of the intake of botanicals in national dietary surveys would provide much-needed data for comprehensive risk and benefit assessments at the European level towards an EC policy-making and regulation of the sector. The first results of the survey were disseminated through numerous presentations before the project ended and through a publication in the journal *PLoS One* 2014 (IF in 2013/2014: 3.53) (see Annex IVc).

Chapter 4: Although limited by a small sample size and a lack of "composition data" (actual amounts of the botanical ingredients), our study represents a first attempt (and hopefully not the last) to explore the relationship "BMI-PFS consumption" in six EU countries. Findings should encourage the research community to carry out further studies on this topic. Future studies should as much as possible be long-term, with large sample sizes from the general population (i.e. PFS consumers and non-consumers, ideally as part of regional/national health/nutrition/CAM-use surveys), and that allow collecting label data on ingredients amounts and dosages. This additional information would help elucidate the many unknowns about the marketing, consumption and effectiveness of PFS specifically used as a strategy for body weight control (in some countries like Spain rather prevalently). It is important to keep on gathering data on the weight-loss botanicals that are being consumed, why and how they are being consumed, and if there are any differences between consumers and non-consumers of these botanicals in terms of their body weight indicators (BMI, WC, etc) and other aspects of health. This research was presented as a poster at the *III World Congress of Public Health Nutrition*, Las Palmas de Gran Canaria, 9-12 November 2014 (see Annex IVd). The article is pending submission to one of the following journals (IF in 2013-2014): 1) *Phytomedicine* (2.877) or 2) *Plant Foods For*

Human Nutrition (2.416) or 3) *Phytotherapy Research* (2.397) or 4) *Planta Medica* (2.339).

4. References

This section includes n=298 alphabetically ordered references cited in all the previous sections.

5. Annexes

This section contains supplementary information to the different sections of this thesis, including: the recommendations of the WHO 2008 Expert Consultation on waist circumference and waist-hip ratio; the PlantLIBRA PFS Consumer Survey’s screening questionnaire; the PlantLIBRA PFS Consumer Survey’s main questionnaire; and the dissemination material (two published articles, one submitted article and one presented poster).

6. Resumen en castellano de la tesis doctoral: aspectos más relevantes

(“Spanish summary of the PhD thesis: most relevant aspects”)

This summary in Spanish of the most relevant aspects of the thesis is included in order to comply with the rules of the "Regulations for the preparation, tribunal, defence and evaluation of doctoral theses, Chapter I, Article 2" (Royal Decree 1393/2007), of the University of Las Palmas de Gran Canaria.

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6 Resumen en castellano de la tesis doctoral: aspectos más relevantes

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Abbreviations

BMI	Body Mass Index
CAM	Complementary and alternative medicine
EC	European Commission
EFSA	European Food Safety Authority
ENCAT	Evaluations of the Nutritional Status of the Catalan Population
EU	European Union
GHO	Global Health Observatory
ICO	International Congress of Obesity
IDF	International Diabetes Federation
IOTF	The International Obesity Task Force
IR	Increased risk (of metabolic complications)
OR	Odds ratio
PFS	Plant food supplement(s)
PlantLIBRA	PLANT Food Supplements: Levels of Intake, Benefit and Risk Assessment
SES	Socio-economic status
SIR	Substantially increased risk (of metabolic complications)
WC	Waist Circumference
WHO	World Health Organization
WHR	Waist–Hip-Ratio

0. Rationale, aim & specific objectives

0. RATIONALE, AIM AND SPECIFIC OBJECTIVES

Rationale

Overweight and obesity prevalence rates have been increasing worldwide in the last 3 decades. This is the case in the adult population from Catalonia, Spain.

Overweight and obesity are multi-factorial chronic diseases.

There are many strategies used by individuals for body weight control/loss. Although the diets of all sorts and physical activity are the most popular methods, also relevant ones are tobacco smoking (i.e. smokers are reluctant to give up smoking under the fear that they will gain body weight if they do so) and the usage of weight-loss plant food supplements (PFS).

This PhD thesis has been motivated by the following questions:

1. What are the prevalence rates of overweight and obesity in the Catalan adult population in two different points in time (1992-1993 and 2002-2003)?
2. Do socioeconomic (occupation and education) and sociodemographic (gender, age and population of residence size) factors relate to these prevalence rates?
3. Do popularly used weight-control strategies such as tobacco smoking (in Catalonia) and PFS consumption (six EU countries) relate to these prevalence rates?

Aim

This thesis aims firstly to respond to the questions posed on the rationale, with the intention of identifying groups within the Catalan adult population who -according to their SES or their smoking habits- may be more vulnerable to excess body weight and fatness; in addition, it aims to ascertain if tobacco smoking or PFS usage to control/lose weight has any relationship with overweight or obesity. Finally, it aims to contribute to the scientific literature on overweight and obesity.

Specific objectives

The objectives of chapter 1 are two: a) to evaluate the trends (1992–2003) of overweight and obesity prevalence rates in the adult population of Catalonia, Spain, and b) to explore the influence of some socio-economic (occupation and education), and socio-demographic (gender, age and population of residence size) variables on these prevalence trends.

Chapter 2 has the objective of showing trends in the relationship between smoking history and general overweight/obesity, and between smoking history and central fatness in an adult Catalan population.

Chapter 3 has the objective to provide an overview of the characteristics and usage patterns of PFS consumers in six European countries. This chapter also contextualizes the work carried out in the next research chapter.

Finally, chapter 4's objectives are two: a) to provide an overview of the PFS botanical ingredients consumed for "body weight reasons" and by "overweight/obesity dieters" in six European countries, and b) to explore the relationship between the consumption of these botanical ingredients and the self-reported body mass index (BMI) of their consumers.

1. Background

1. BACKGROUND

This section introduces the main research objectives developed in the thesis. Section 1.1 shows the importance of the problems of overweight and obesity (excess body weight and adiposity) in today's society. Obesity and overweight are defined, weight and body fat measuring techniques are explained, and indicators of overall weight and abdominal fat used in the empirical analysis (Body Mass Index –BMI- and Waist Circumference -PC) are described. Prevalence rates and trends of overweight and obesity at global, European and Spanish level are also shown; determinants of overweight and obesity and the effects that overweight and obesity have on health are summarized. All these aspects have been extensively described in numerous articles and therefore only a summary of the main inputs is presented in order to contextualize the contributions that are made in research chapters 1, 2 and 4 of the thesis. In these chapters the relationship between obesity and overweight and socio-economic and socio-demographic characteristics of the population (chapter 1), smoking history (chapter 2), and consumption of plant food supplements (PFS) (chapter 4) is analyzed.

Chapters 1 and 2 of the thesis have used population samples and datasets obtained from the Catalan Nutrition Surveys (ENCAT 1992-1993 and 2002-2003). The characteristics of these surveys are not described in this introductory section, since they have been widely described in numerous scientific articles published in international journals. The most relevant publications of ENCAT have been cited in the methodological sections of chapters 1 and 2.

Furthermore, this section pays special attention to describing the PlantLIBRA Consumer Survey 2011-2012. This survey was conducted within the framework of the European Project PlantLIBRA, in which the Foundation for Nutritional Research-FIN participated. The survey was conducted under the leadership of Professor Lluís Serra Majem and it was coordinated by the author of this thesis. Its data have been used in this thesis to analyze the consumption of PFS in 6 countries of the European Union (EU) (chapter 3) and to analyze the relationship between BMI and PFS use (chapter 4). The main reason for including a detailed description of the survey is that its development is very recent and there are few articles that have used it. It is also important to note that to date there is very little literature that analyzes the consumption of PFS, their marketing and the profile of the consumers of these products. Finally, the development of the survey and the creation of this database is considered an important methodological contribution of this thesis.

With this in mind, section 2.2 introduces various concepts and definitions used in the preparation of survey material, it describes the methodology used and explains the main features of the database. Moreover, the relevant aspects of the PFS market and its regulation, the evolution of the body weight control industry in recent years and the classification of the botanicals used in weight control/loss are also described.

1.1 Obesity: excess body weight and adiposity – an overview

Obesity is characterised by altered body composition with increased adiposity. When applying the analysis of body composition, cases of obesity are defined when percentages of adipose tissue are above 33% in women and over 25% in men (Serra-Majem & Bautista 2013).

Obesity is a multifactorial chronic disease whose origins involve environmental and genetic factors (Serra-Majem & Bautista 2013; Varela-Moreiras *et al.* 2013). A high percentage of obesity cases show a clear environmental component (related to sedentary habits, inadequate dietary habits and other lifestyle factors) that causes a positive energy balance and, as a consequence, the gradual accumulation of fatty tissue. From the genetics perspective, it is currently known that obesity is a polygenic disease. Moreover there is an incomplete understanding of its physiopathology, for which it is difficult to discern the role of the different polymorphisms and their interaction with environmental factors (Serra-Majem & Bautista 2013).

The International Obesity Task Force (IOTF) and the World Health Organization (WHO) have declared obesity, as the epidemic of the 21st century due to the dimensions acquired within the last few decades, its impact on morbi-mortality, quality of life and related healthcare costs. WHO recognizes the impact obesity has on the development of the most prevalent chronic diseases in our society: type 2 diabetes, cardiovascular diseases, musculoskeletal pathologies and an increasing number of certain cancers. Moreover, increased body weight also leads to the onset of depression, impaired cognitive function (Varela-Moreiras *et al.* 2013) and disorders related to body image, self-esteem, etc, resulting in impaired social interactions (Serra-Majem & Bautista 2013). There is increasing emphasis on the distribution of abdominal fat and its role in increasing cardiovascular risk.

Obesity in a society results in important direct and indirect economic costs, as well as significant increases in social and health services (medical visits, absenteeism, loss of autonomy, special needs, etc) (Serra-Majem & Bautista 2013; Varela-Moreiras *et al.* 2013).

Prevention of excess body weight/adiposity is essential since once the obesity level is reached by an individual, it is associated with a large degree of therapeutic failures and the tendency towards relapse (Serra-Majem & Bautista 2013). A multifactorial disease such as obesity requires a multidisciplinary preventive approach (Varela-Moreiras *et al.* 2013).

1.1.1 Measuring body weight and fatness

Power et al. suggested that “an ideal measure of body fat should be accurate in its estimate of body fat; precise, with small measurement error; accessible, in terms of simplicity, cost and ease of use; acceptable to the subject; and well documented, with published reference values”. They further comment that “no existing measure satisfies all these criteria” (Power, Lake & Cole 1997; Lobstein, Baur & Uauy 2004).

Adiposity is measured using a range of settings and methods. There are both direct and indirect methods for assessing and evaluating fatness:

- Direct measures of body composition provide an estimation of total body fat mass and several components of fat free mass. Such techniques include underwater weighing, magnetic resonance imaging (MRI), computerized axial tomography (CT or CAT) and dual energy X-ray absorptiometry (DEXA). The methods are used predominantly for research and in tertiary care settings, but may be used as a “gold standard” to validate anthropometric measures of body fatness (Goran 1998).
- Indirect measures refer to the anthropometric measures of relative adiposity include among others waist, hip and other girth measurements, skinfold thickness and indices derived from measured height and weight such as Quetelet’s index (BMI or W H-2), the ponderal index (W H-3) and similar formulae. All anthropometric measurements rely to some extent on the skill of the person taking the measure, and their relative accuracy as a measure of adiposity must be validated against a ‘gold standard’ measure of adiposity (Lobstein, Raur & Uauy 2004).

Table 1 includes a brief description of these direct and indirect methods, as well as comments on the strengths and weaknesses of these different methods used for population and clinical judgements.

Table 1. Methods for measuring body composition.

Method	**Description**	**Comments: advantages (A) and disadvantages (D)**
Direct measures		
Underwater weighing (hydro-densitometry)	Fat has a lower density than lean tissue, and by measuring the density of the whole body the relative proportions of each component can be determined. If total body density and the specific densities of fat and fat-free mass are known, an equation can be generated for converting total body density to percentage body fat (Goran 1998).	(D): Requires a person to hold their breath underwater, and is unsuitable for use in young children or in older subjects who lack water confidence. There are theoretical concerns about the assumptions used to translate density measurements into estimates of fat mass and fat-free mass, both among normal children and the obese.
Magnetic resonance imaging (MRI)	MRI provides a visual image of adipose tissue and non-fat tissue. Total body fat volume, total fat mass and percentage fat mass can be estimated.	(A): MRI can accurately and reliably distinguish intra-abdominal from subcutaneous fat. (D): MRI is expensive, time consuming and must be performed in a major medical facility. The procedure takes approximately 20 min, and requires the subject to lie still, enclosed in a scanner, and may be unsuitable for young children.
Computerized tomography (CT)	CT scans produce high-resolution X-ray-derived images and can identify small deposits of adipose tissue. Total and regional body fat can be calculated, as well as percentage body fat.	(A): The procedure allows intra-abdominal and subcutaneous fat to be quantified with a high degree of accuracy and reliability. (D): The equipment is expensive and must be operated by a skilled technician. The procedure involves significant radiation exposure, takes 20 min and requires the subject to lie still within the scanner, so is unsuitable for routine use in children unless clinically indicated.

Table 1. *Continued.*

Dual-Energy X-ray Absorptiometry (DEXA)	DEXA is based on the principle that transmitted X-rays at two energy levels are differentially attenuated by bone mineral tissue and soft tissue, and the soft tissue component is subdivided into fat and lean tissue by using experimentally derived calibration equations (Goran *et al.*1996).	(A): It has a high correlation with CT scan data in determining total fat mass (Goran *et al.*1998). The procedure delivers lower radiation exposure than CT and is thus more suitable for use in children and adolescents. (D): DEXA cannot distinguish between intra-abdominal and subcutaneous fat. The test must be performed in a major medical facility with the DEXA equipment, the equipment is expensive and must be operated by a skilled technician, and the procedure may take up to 20 min and requires a very cooperative subject, therefore making it unsuitable for children aged less than 6 years. DEXA has not been fully evaluated in healthy child or adolescent populations or in very obese people.
Bioelectrical impedance analysis (BIA)	BIA is not strictly a direct measure of body composition, being based on the relation between the volume of a conductor (the body), the conductor's length (height) and its electrical impedance (Wells 2001). BIA assumes fat mass is anhydrous and that conductivity reflects fat-free mass. Prediction equations estimate the fat-free mass from the measured impedance and, by subtraction, the fat mass.	(A): BIA measurements can be taken quickly and inexpensively, it is relatively non-invasive and has high inter- and intra-observer reliability. (D): It requires equations specific to the instrument used and for the population under investigation, and the measurement may vary with hydration status and ethnic status (Wabitsch *et al.* 1996). Although gaining acceptance in a range of settings, the limitations of BIA are sometimes overlooked.
Air-displacement plethysmography	A subject's volume is determined indirectly by measuring the volume of air the subject displaces when sitting inside an enclosed chamber. Adjustment for thoracic gas volume is made. Once body volume and mass are known, the principles of densitometry are applied to estimate percentage body fat.	(A):Air-displacement plethysmography measurements are comfortable, relatively quick, non-invasive and can accommodate a wide range of body types. (D): Subjects should be reasonably cooperative (for accurate measurement the subject should breathe through a tube and wear a nose clip) and hence the technique may be unsuitable for younger children. Again, there are theoretical concerns about the assumptions used to calculate body fat (Fields *et al.* 2002).

Table 1. *Continued.*

Indirect measures		
Body mass index (BMI)	BMI is defined as weight (kg) /height squared (m^2), and is widely used as an index of relative adiposity among children[a], adolescents and adults. Among adults, the WHO recommends that a person with a BMI of 25 kg m-2 or above is classified overweight, while one with a BMI 30 kg m-2 or above is classified obese (WHO 2000) although revisions of these guidelines are being proposed for certain populations (Deurenberg-Yap *et al.* 2002). For children, various cut-off criteria have been proposed based on reference populations and different statistical approaches.	(A): BMI is more accurate when height and weight are measured by a trained person rather than self-reported. Measurement of height and weight has a high subject acceptance, which is particularly important for adolescents who may be reluctant to undress (measures are normally taken in light clothing, without shoes). There is low observer error, low measurement error and good reliability and validity. (D): BMI may not be a sensitive measure of body fatness in people who are particularly short, tall or have an unusual body fat distribution, and may misclassify people with highly developed muscles. Hence two people with the same amount of body fat can have quite different BMIs (Sardinha *et al.* 1999). There may also be racial differences in the relationship between the true proportion of body fat and BMI (Wang *et al.* 1994).
Waist circumference (WC) and Waist-to-hip ratio (WHR)	WC is an indirect measure of central adiposity. Central adiposity is strongly correlated with risk for cardiovascular disease in adults (Ross *et al.* 1996) and an adverse lipid profile and hyperinsulinaemia in children (Freedman *et al.* 1999). WC is measured at the minimum circumference between the iliac crest and the rib cage using an anthropometric tape. W-to-hip ratio has been used among adults to identify people with high central adiposity. WC is measured as above and hip circumference is measured at the maximum protuberance of the buttocks. The ratio is then calculated.	(A): Waist and hip circumferences are easy to measure with simple, low-cost equipment, have low observer error, offer good reliability, validity and low measurement error. (D): There are no accepted cutoff values for the classification of overweight and obesity based on these measures, and there have been few studies of the relation between central adiposity and the metabolic disturbances associated with excess visceral fat among children and adolescents. WC and hip circumference are highly age dependent, and it is not recommended to use the ratio between them without first considering each measure separately (Power *et al.* 1997).

Table 1. *Continued.*

Skin-fold thickness	Skin-fold thickness can be measured at different sites on the body (e.g. triceps, subscapular) using skin-fold callipers. Prediction equations can then be used to estimate fat mass and percentage fat from the skin-fold measurements. New methods for measuring skin fold using portable echography equipment are under development.	(A): Skin-fold thickness uses simple equipment and offers only a moderate respondent burden, and has the potential to determine total body fat and regional fat distribution. (D): Skin-fold thickness varies with age, sex and race, and the equations relating skin-fold thickness at several sites to total body fat need to be validated for each population. Measurement requires training and intra- and inter-observer reliability is poor (Wells 2001). In very obese individuals the measurement of triceps skin-fold or other skin-fold thicknesses may not be possible. The relationship with metabolic problems is unclear.
Other anthropometric measures: 1) the Ponderal Index; 2) the Conicity Index; 3) The Body Shape Index.	Various alternatives to the weight-to-height ratio have been developed examining different powers of N in the formula weight/heightN, such as the Ponderal Index (w h^{-3}). 'N' is sometimes referred to as the Benn index. The Conicity Index, is defined as WC/(0.109 x square root of weight/height). The Body Shape Index (ABSI) is the most recent index defined as WC/$BMI^{2/3}$ $height^{1/2}$.	(A): 1) and 2) measures have high subject acceptance and there is low observer error, low measurement error and good reliability and validity; 3) Body shape, as measured by ABSI, appears to be a substantial risk factor for premature mortality in the general population derivable from basic clinical measurements. ABSI expresses the excess risk from high WC in a convenient form that is complementary to BMI and to other known risk factors (Krakauer 2012). (D): 1) and 2) measures - as with BMI, height and weight are more accurate when measured by a trained person rather than self-reported; 3) More cohorts are needed to delineate the limits of ABSI's utility and further studies about ethnic specificities of ABSI are needed and warranted (He & Chen 2013). None of these indices is widely used at present.

Source: adapted from Lobstein *et al.* 2004.
[a]For children, various cut-off criteria have been proposed based on reference populations and different statistical approaches (Lobstein *et al.* 2004).

1.1.2 The body weight and fatness measures used in this thesis

Overweight and obesity occur when excess fat accumulates in the human body, posing a risk to health. Despite the limitations mentioned in the previous section, current definitions are based on both the BMI and the WC (ICO 2010). A gain in body weight or WC is indicative of increasing health risk.

1.1.2.1 Body Mass Index

The "Quetelet index" – as it was known until 1972, when Ancel Keys (1904-2004) termed it the "Body Mass Index" (Keys *et al.* 1972)-, was described in 1832 by the Belgian mathematician Adolphe Quetelet (Eknoyan 2007) and it is a measure for human body shape based on an individual's mass and height.

The WHO defines the BMI as "a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults"; Table 2 includes the international classification of adult underweight, overweight and obesity according to BMI that has been proposed by the WHO (WHO 1998; WHO 2014: BMI). It is defined as the "weight in kilograms divided by the square of the height in metres (kg/m^2)". For example, an adult who weighs 80kg and whose height is 1.80m will have a BMI of 24.7.

$$\text{BMI} = 80\ \text{kg}/(1.80\ \text{m}^2) = 80/3.24 = 24.7\ \text{kg/m}^2$$

In countries where the weight is measured in pounds and the height in inches, the formula would be adapted as follows: BMI = [weight(lb)/height(in))^2] x 703)

Table 2: The International Classification of adult underweight, overweight and obesity according to BMI.

Classification	**BMI (kg/m^2)**	
	Principal cut-off points	**Additional cut-off points**
Underweight	**<18.50**	**<18.50**
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 - 16.99	16.00 - 16.99
Mild thinness	17.00 - 18.49	17.00 - 18.49
Normal weight	**18.50 - 24.99**	**18.50 - 22.99** **23.00 - 24.99**
Overweight	**≥25.00**	**≥25.00**
Pre-obese	25.00 - 29.99	25.00 - 27.49 27.50 - 29.99
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49 32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49 37.50 - 39.99
Obese class III	≥40.00	≥40.00

Source: WHO 2014: Global Database on BMI, adapted from WHO 1995, WHO 2000 and WHO expert consultation 2004.

Adult BMI values are age-independent and the same for both sexes. However, BMI may not correspond to the same degree of fatness in different populations due, in part, to different body proportions. The health risks associated with increasing BMI are continuous and the interpretation of BMI gradings in relation to risk may differ for different populations (WHO 2014: Global Database on BMI). For example, the interpretation of the BMI cut-offs in Asian and Pacific populations raised a debate due to the increasing evidence that the associations between BMI, percentage of body fat, and body fat distribution differ across these populations and therefore, the health risks increase below the cut-off point of 25 kg/m^2 that defines overweight in the current WHO classification (WHO/IASO/IOTF 2000; James *et al.* 2002). In order to shed the light on this debate, WHO convened the Expert Consultation on BMI in Asian populations (Singapore, 8-11 July, 2002) (WHO expert consultation 2004).

The WHO Expert Consultation concluded that the proportion of Asian people with a high risk of type 2 diabetes and cardiovascular disease is substantial at BMI's lower than the existing WHO cut-off point for overweight (= 25 kg/m^2). However, the cut-off point for observed risk varies from 22 kg/m^2 to 25 kg/m^2 in different Asian populations and, for high risk, it varies from 26 kg/m^2 to 31 kg/m^2. The Consultation, therefore, recommended that the current WHO BMI cut-off points (Table 1) should be retained as the international classification (WHO expert consultation 2004). However, they also recommended that the cut-off points of 23, 27.5, 32.5 and 37.5 kg/m^2 were to be added as points for public health action: therefore, for reporting purposes, and with a view to facilitating international comparisons, countries should use all categories (i.e. 18.5, 23, 25, 27.5, 30, 32.5 kg/m^2, and in many populations, 35, 37.5, and 40 kg/m^2) (WHO expert consultation 2004).

A WHO working group was formed by the WHO Expert Consultation (WHO expert consultation 2004) and is currently undertaking a further review and assessment of available data on the relation between WC and morbidity and the interaction between BMI, WC, and health risk (WHO 2014: Global Database on BMI).

1.1.2.2 Waist circumference

Waist circumference (WC) has more recently been considered to classify obesity, as the distribution of body fat has been found to be important and carrying it around the abdomen has been found to be especially unhealthy. The WHO defines disease risk on the basis of both BMI and WC (see Table 3).

As reported in the "2008 WHO Expert Consultation on WC and waist-hip ratio" (WHR), different organizations have given recommendations on both WC and WHR[1] (WHO 2008). These organizations and their recommendations are as follows:

- *World Health Organization*

A number of WHO publications make recommendations for WC and WHR. Recommendations about abdominal obesity and WC have been made as one of the components of metabolic syndrome in a report on diabetes mellitus (WHO 1999), under the definition of metabolic syndrome. According to this report, the working definition of metabolic syndrome is a condition characterized by "glucose intolerance, impaired glucose tolerance or diabetes mellitus, and/or insulin resistance together with two or more components listed below", which includes abdominal obesity in addition to raised arterial pressure, raised plasma triglycerides and microalbuminuria. Abdominal obesity is further defined as WHR above 0.90 for males and above 0.85 for females, or a BMI above 30.0 (WHO 2008).

The report of the WHO Expert Consultation on Obesity (WHO 2000) highlighted the "need to develop sex-specific WC cut-off points appropriate for different populations". That report provides a table as an example of sex-specific WC and risk of metabolic complications associated with obesity in Caucasians. The table is based on the increased relative risk observed in the Netherlands from a random sample of 2183 men and 2698 women aged 20–59 years (Han *et al*. 1995). The recommended sex-specific cut-off points are 94 cm (men) and 80 cm (women) for increased risk, and 102 cm (men) and 88 cm (women) for substantially increased risk.

Based on these two WHO reports, the recommendations often attributed to WHO are shown in Table 3 although those sex-specific cut-off points cited in the report of the WHO Expert Consultation on Obesity (WHO 2000) were an example only and not WHO recommendations (which were included in the WHO 2008 report).

[1] The aim of the expert consultation was to provide guidance that WHO could use to develop recommendations and ultimately provide guidelines for the effective use of specific cut-off points for waist circumference and waist–hip ratio. Making definitive decisions on actual cut-off points was outside the scope of the consultation. However, the expert consultation was asked to advise WHO on how the process of developing actual cut-off points could be moved forward, and to identify any gaps in the data.

Table 3. WHO cut-off points and risk of metabolic complications.

Indicator	Cut-off points	Risk of metabolic complications
Waist circumference	>94 cm (M) >80 cm (W)	Increased
Waist circumference	>102 cm (M) >88 cm (W)	Substantially increased
Waist–hip ratio	≥0.90 cm (M) ≥0.85 cm (W)	Substantially increased

M, men; W, women. Source: WHO 2008.

- *International Diabetes Federation*

The International Diabetes Federation (IDF) has also provided recommendations for cut-offs for WC and WHR (IDF 2006; Zimmet & Alberti 2006). The recommendations of IDF for WC are not only sex specific, but are also population and geography specific. Values are shown in Table 4.

Table 4. International Diabetes Federation cut-off points for different ethnic groups.

	Men	Women
Europids	>94 cm	>80 cm
South Asians, Chinese and Japanese	>90 cm	>80 cm

Source: IDF 2006.

- *United States National Cholesterol Education Program*

Another group of recommendations extensively used are the ones recommended by the experts of the Adult Treatment Panel (ATP) under the auspices of the National Cholesterol Education Program (NCEP) of the NIH's National Heart, Lung, and Blood Institute. The NCEP recommends sex-specific cut-offs of above 102 cm for men and above 88 cm for women (ATP III 2001).

- *Other countries*

The WHO conducted an analysis as part of the preparations for the expert consultation which showed that some countries adhered to one or more of the three recommendations mentioned above (for example, many countries use the WHO cut-off points; or Saudi Arabia, Singapore and Slovakia, use both the IDF and the NCEP recommendations), whereas other countries had their own specific recommendations and others use both options (for example, the Republic of Korea, Saudi Arabia, Singapore, Slovakia and Turkey use the IDF recommendations plus other specified sources). In addition, some countries such as Japan have based their cut-off points on assessment of visceral adipose tissue from computerized tomography – i.e. the extent to which measurements predict intra-abdominal fat rather than disease risk (JSSO, 2002) – and DEXA (Ito *et al.* 2003; WHO 2008).

The WHO's WC and WHR Expert Consultation stated that there is little information on the endorsement of WC and WHR cut-off points at national level by national ministries of health (WHO 2008). They also stated that the most popular cut-off points used worldwide were the ones attributed to two reports from WHO (WHO 1999; WHO 2000). Moreover, they recognized that the IDF recommendations and the NCEP cut-off points were frequently used in research or national surveys in many countries, although the rationale for the choice and use of a specific recommendation was often unknown and unclear (WHO 2008). Finally, they mentioned that several other countries have developed their own recommendations and cut-off points, however, some of these are simply suggested or used in specific populations in published studies, rather than being national recommendations (WHO 2008).

Rationales for selecting the cut-off points of WC and WHR vary, but are generally based on indices of sensitivity and specificity and their trade of (sensitivity measures the proportion of actual positives correctly identified as such, and specificity measures the proportion of actual negatives correctly identified as such) (WHO 2008). In some cases, there are multiple specific cut-off points for different diseases or risk factors.

The consultation concluded that due to the relative low difficulty of obtaining WC, its use is favoured over WHR. Moreover, there was insufficient data on other proxy measures (e.g. waist–height ratio) to suggest giving them any priority at present. Finally, although BMI and abdominal adiposity measures may be highly correlated, it is preferable to obtain a BMI where possible, and consider the utility of using the two indicators together as suggested by the NHLBI Obesity Education Initiative (NHLBI Obesity Education Initiative 2000) and shown in Table 5 (WHO 2008).

Table 5. Combined recommendations of BMI and WC cut-off points made for overweight or obesity, and association with disease risk.

	BMI	Obesity class	Disease risk (relative to normal weight and WC)	
			Men < 102 cm Women < 88 cm	Men >102 cm Women >88 cm
Underweight	<18.5			
Normal	18.5–24.9			
Overweight	25.0–29.9		Increased	High
Obese	30.0–34.9	I	High	Very high
	35.0–39.9	II	Very high	Very high
Extreme obesity	>40.0	III	Extremely high	Extremely high

Source: NHLBI Obesity Education Initiative 2000. BMI=Body Mass Index; WC=Waist circumference.

Recommendations

The expert consultation agreed that the anthropometric indicators and measures used previously (i.e. BMI, WC and waist–hip ratio) are predictive of the risk of chronic disease. Hence, any WC and waist–hip ratio cut-off points developed following the process recommended by the consultation (see Annex I) could be used alone or in conjunction with BMI.

1.1.3 Global, European and Spanish overweight and obesity prevalence rates and trends

According to the WHO, overweight and obesity are increasing in prevalence and, worldwide, are the fifth cause of death in the ranking of risk factors, behind high blood pressure, tobacco use, high blood glucose, and physical inactivity (WHO 2009). In high and middle income countries, where the prevalence of overweight and obesity among the adult population already exceeds 50%, they rank third among risk factors causing death, behind high blood pressure and tobacco use (WHO 2009).

Global data

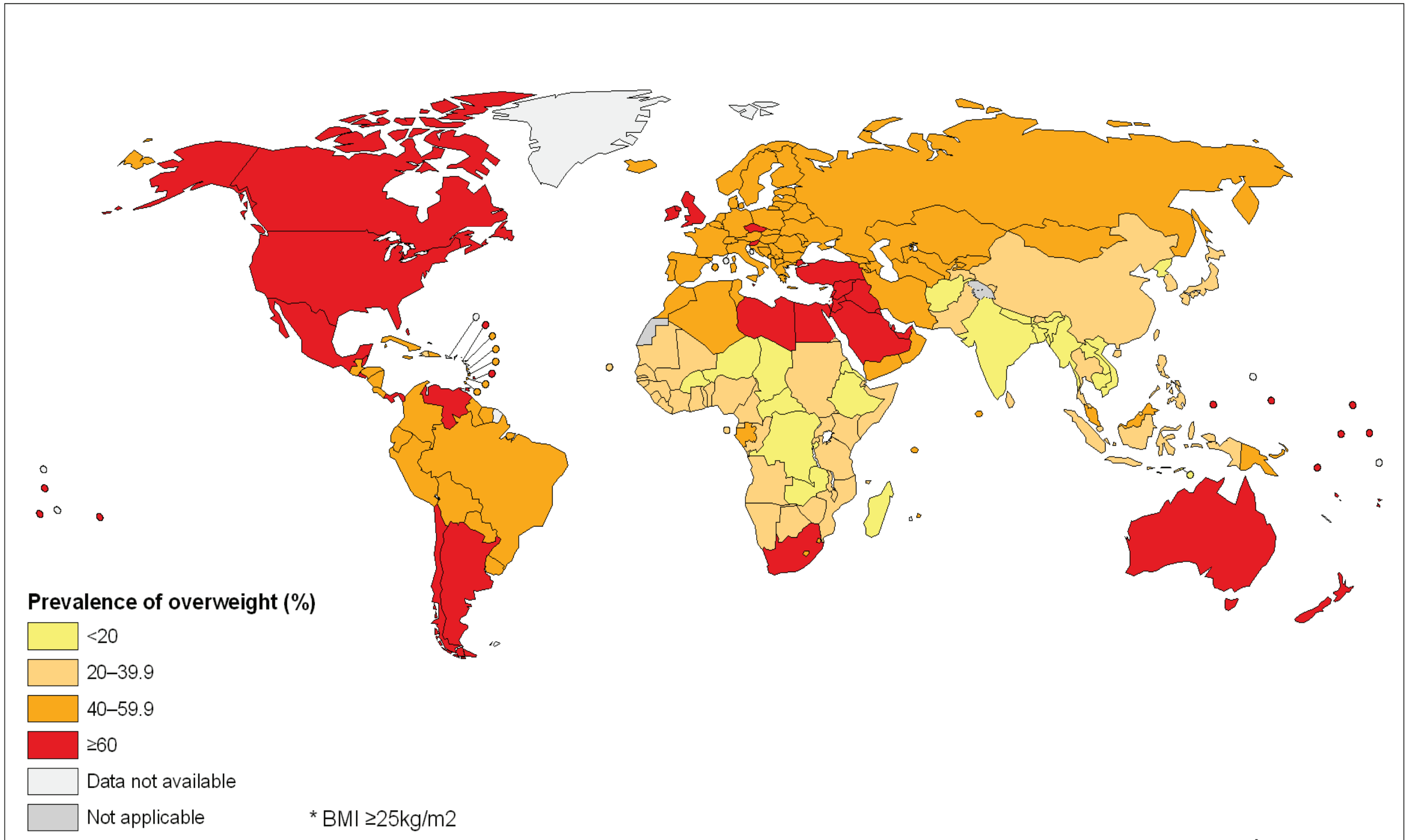
In 1980, the worldwide prevalence of adult obesity was 5% for men and 8% for women (WHO 2009).

In 2003, the WHO reported 1.1 billion overweight individuals and 300 million obese individuals (Garcia-Alvarez *et al.* 2006; WHO 2003), 10% of which were overweight or obese children (Garcia-Alvarez *et al.* 2006; Haslam & James 2005). In the same report they also stated that, since 1980, worldwide obesity had nearly doubled, obesity prevalence rates had increased threefold in Northern America, the United Kingdom, Central and Eastern Europe, Pacific Islands, Australia and China (WHO 2003); a few years later, Townsend reported that in the United States, over 65% of adults were overweight or obese (Garcia-Alvarez *et al.* 2006; Townsend 2006).

More recently, in its Global Health Observatory (GHO) (WHO 2009), the WHO reported that, in 2008, more than 1.4 billion adults aged 20+ were overweight, this is 35% of adults over 20; of these, over 200 million men (10% vs. 5% in 1980, a 2-fold increase) and nearly 300 million women (14% vs. 8% in 1980, just under a 2-fold increase) were obese worldwide i.e. 11% of adults over 20 (a total of more than half a billion) (WHO 2009; WHO 2013).

Figures 1 and 2 show WHO's global distribution of adult BMI overweight and obesity in 2008. It can be observed that obesity prevalence rates were highest (≥60% of the population aged 20-and-over) in Alaska, the United States of America, Mexico, Venezuela, Libya, Egypt, Israel, Syria, Jordan, Saudi Arabia, United Arab Emirates and South Africa; while overweight prevalence rates reached 60% also in these countries, as well as in Canada, Panama, Chile, Argentina, Ireland, the United Kingdom, the Czech Republic, Turkey, Iraq, Australia and New Zealand.

Figure 1. Prevalence of overweight*, ages 20+, age standardized. Both sexes, 2008.

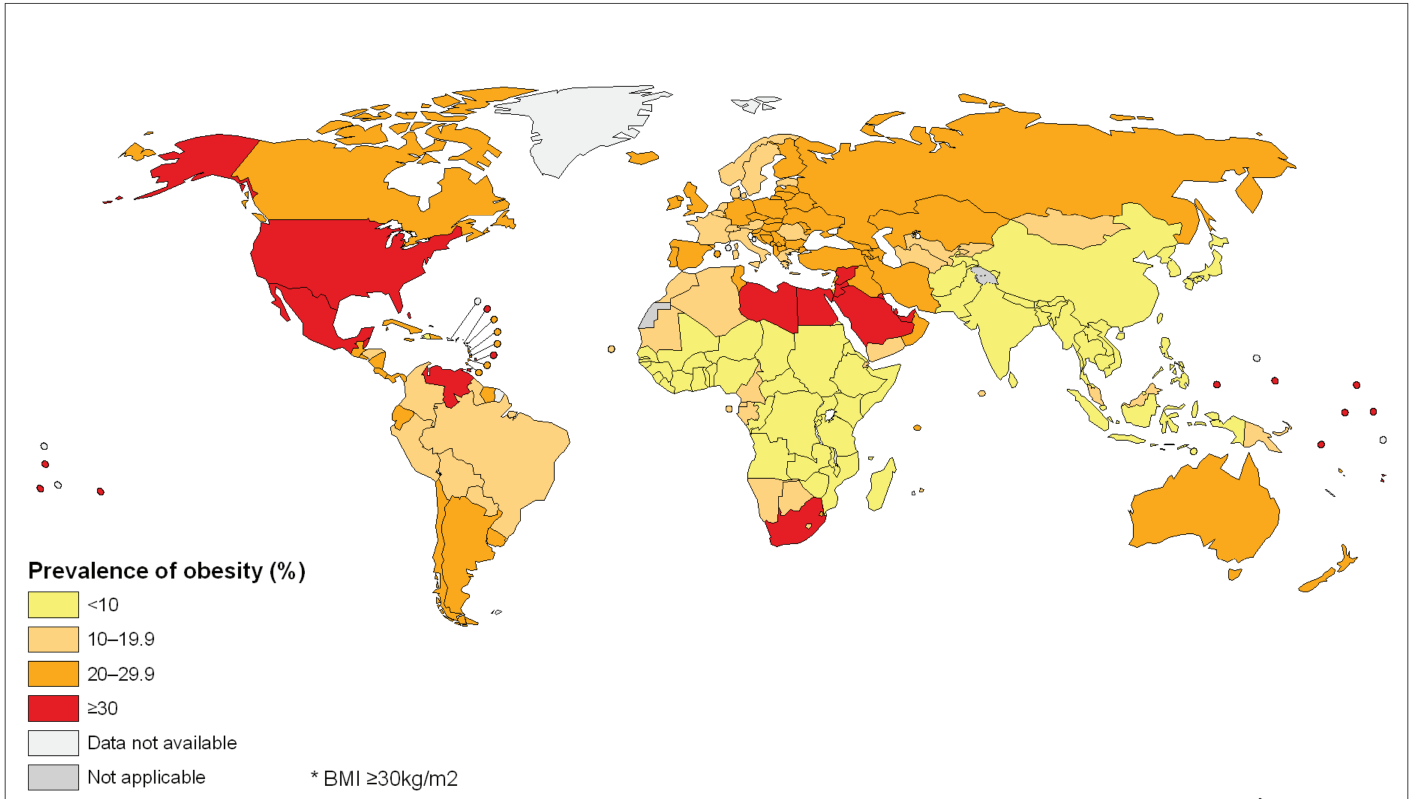


The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which

Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

Source: WHO 2011.

Figure 2. Prevalence of obesity*, ages 20+, age standardized. Both sexes, 2008.



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization

World Health Organization

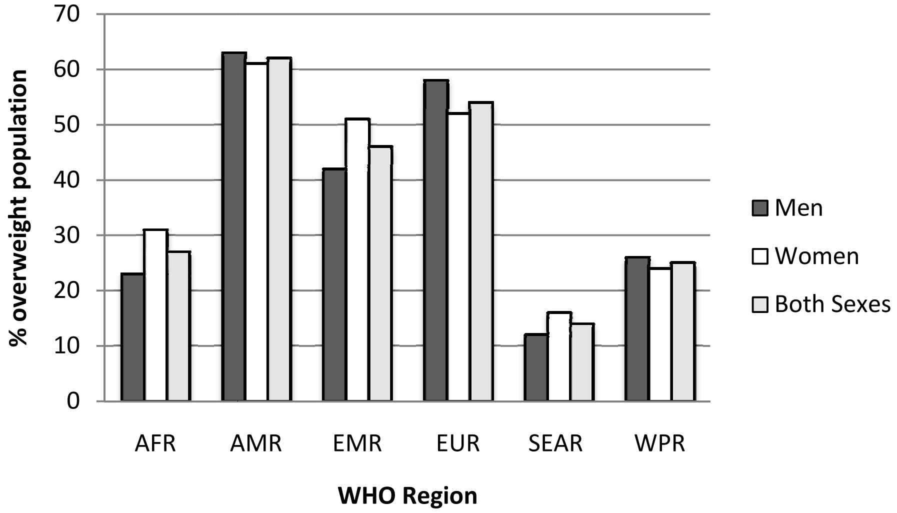
Source: WHO 2011.

Moreover, the WHO recognizes that overweight and obesity prevalence rates are increasing both in developed and developing societies (Garcia-Alvarez *et al.* 2006; WHO 2003) and that 65% of the world's population live in countries where overweight and obesity kills more people than underweight (WHO 2013). The WHO has very recently reported a very alarming fact that evidences this increasing trends and compromises global future health: “more than 40 million children under the age of five were overweight in 2011”; and they insist in the statement that obesity is preventable (WHO 2013).

The WHO facts and figures are in line with those of the IASO/IOTF which refers to obesity as “the global epidemic”, and whose recent analysis (2010 data) estimates that approximately 1.0 billion adults are currently overweight (BMI 25-29.9 Kg/m^2), and a further 475 million are obese. They add that when Asian-specific cut-off points for the definition of obesity (BMI>28 kg/m^2) are taken into account, the number of adults considered obese globally is over 600 million. Moreover, globally, IASO/IOTF estimate that up to 200 million school-aged children are either overweight or obese, of those 40-50 million are classified as obese (IASO/IOTF 2012).

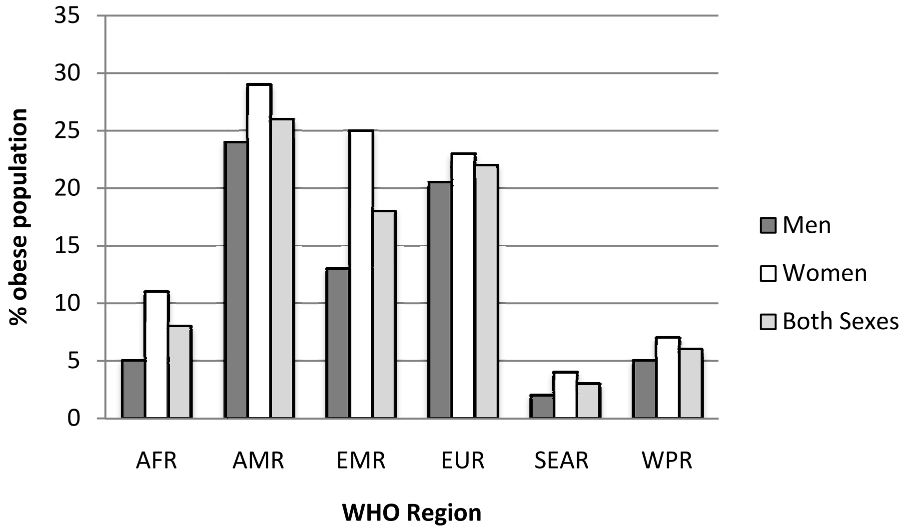
The GHO also reported the 2008 prevalence of overweight and obesity by WHO region (WHO 2009). Figures 3 and 4 show that the prevalence rates of overweight and obesity were highest in the WHO Regions of the Americas (62% for overweight in both sexes, and 26% for obesity) and lowest in the WHO Region for South East Asia (14% overweight in both sexes and 3% for obesity). In the WHO Region for Europe and the WHO Region for the Eastern Mediterranean and the WHO Region for the Americas over 50% of women were overweight (Figure 3). For all three of these regions, roughly half of overweight women were obese (23% in Europe, 24% in the Eastern Mediterranean, 29% in the Americas) (Figure 4). Moreover, in all WHO regions women were more likely to be obese than men. In the WHO regions for Africa, Eastern Mediterranean and South East Asia, women had approximately twice the obesity prevalence of men.

Figure 3. Overweight prevalence in adults aged 20+ years (age standardized), by WHO Region, gender and income level.



Source: Adapted from WHO's Global Health Observatory (WHO, 2009), year 2008.

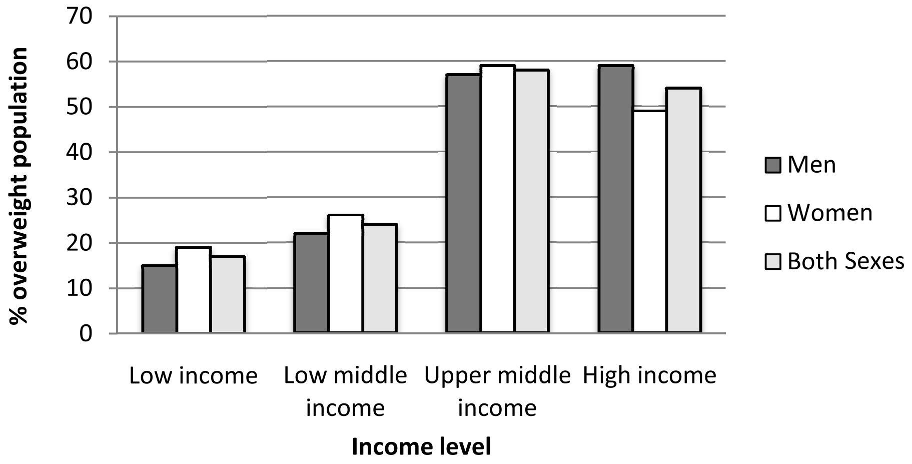
Figure 4. Obesity prevalence in adults aged 20+ years (age standardized), by WHO Region



Source: Adapted from WHO's Global Health Observatory (WHO, 2009), year 2008.

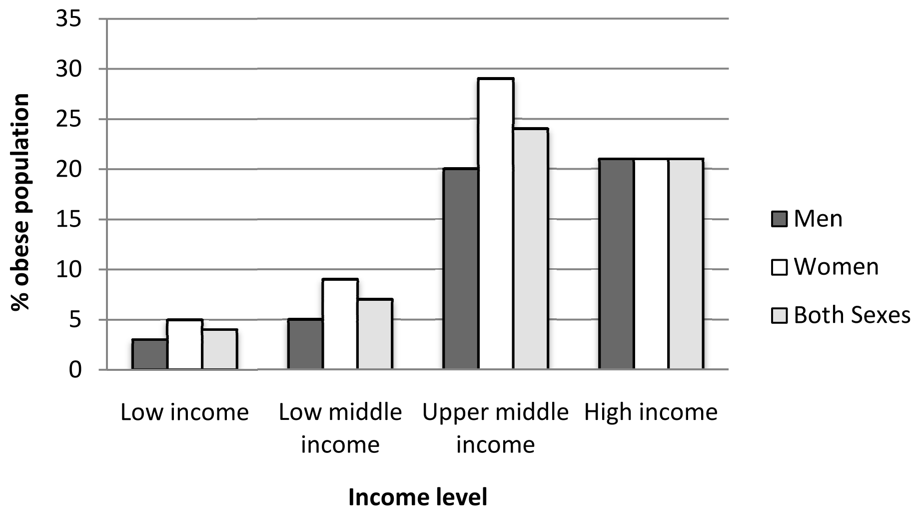
In addition, the GHO reports that the prevalence of elevated BMI increases with income level of countries up to upper middle income levels (WHO 2009). Obesity, unhealthy diets and too little physical activity are often linked to each other and to a far more common cluster of risk factors among people with low versus higher incomes (WHO 2007). In 2008, the prevalence of overweight in high income and upper middle income countries was more than twice that of low and lower middle income countries (Figure 5). Regarding obesity, the difference more than tripled from 7% obesity in both sexes in lower middle income countries to 24% in upper middle income countries (Figure 6). Obesity among women was significantly higher than among men, except for high income countries where it was similar. In low and lower middle income countries women's obesity was approximately twice that of men.

Figure 5. Overweight prevalence in adults aged 20+ years (age standardized), by income level.



Source: Adapted from WHO's Global Health Observatory (WHO 2009), year 2008.

Figure 6. Obesity prevalence in adults aged 20+ years (age standardized), by income level.

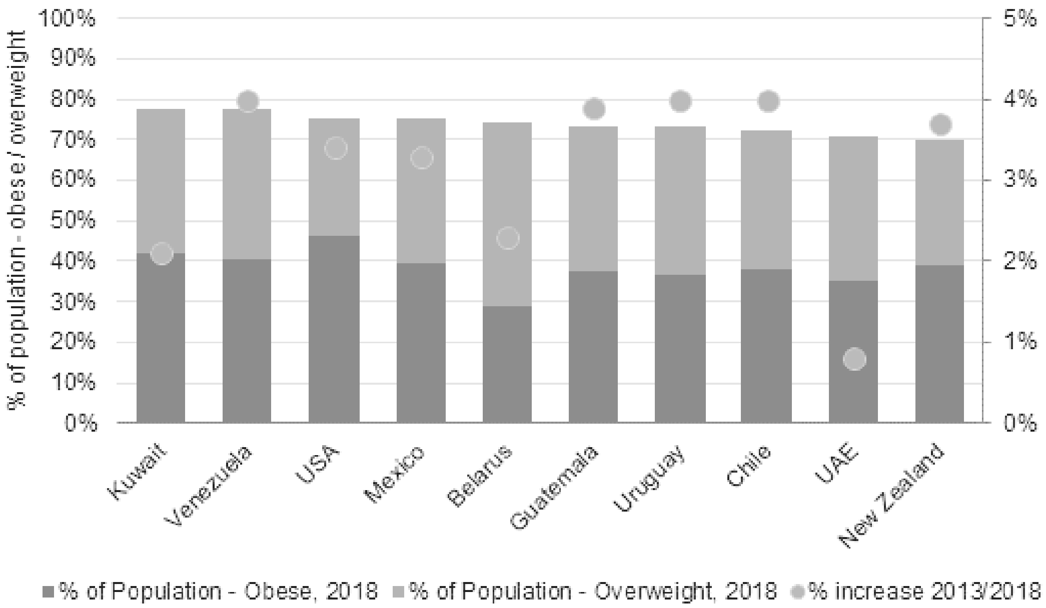


Source: adapted from WHO's Global Health Observatory (WHO 2009), year 2008.

And the future does not augur better expectations. According to the WHO, in 2011, more than 40 million children under the age of five were overweight. Once considered a high-income country problem, overweight and obesity are now on the rise in low- and middle-income countries, particularly in urban settings. More than 30 million overweight children are living in developing countries and 10 million in developed countries (WHO 2013).

Figure 7 shows that by 2018, more than 3 out of 4 people aged 15 and older are projected to be overweight or obese in Kuwait, Venezuela, and Mexico, as well as in the United States (Euromonitor International 2014a).

Figure 7. Countries with the largest overweight and obese populations, 2013/2018



Source: Euromonitor International 2014a.

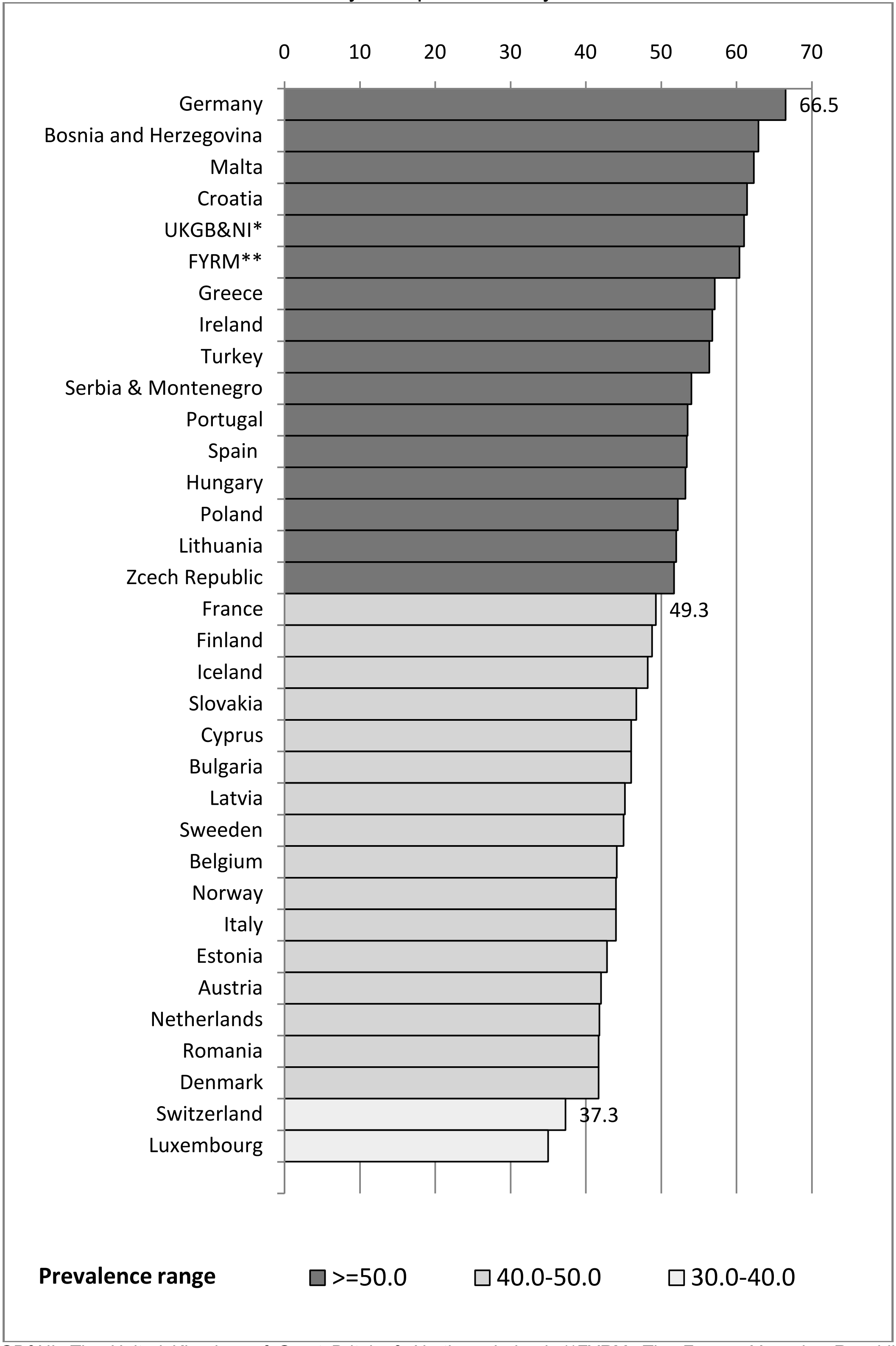
As seen earlier, this is a major cause for concern since being overweight or obese is linked to a series of health complications and is directly responsible for 2.8 million deaths a year according WHO.

European data

The WHO has reported that overweight affects 30-80% of adults in the countries of the European Region (WHO Regional Office for Europe 2007; WHO 2011; WHO Regional Office for Europe 2013). Also that more than 20% of children and adolescents are overweight, and one third of these are obese, alerting that the trend in obesity is especially alarming among children and adolescents. The annual rate of increase in the prevalence of childhood obesity has been growing steadily and the current rate is 10 times that in the 1970s (WHO Regional Office for Europe 2007; WHO 2011; WHO Regional Office for Europe 2013). This contributes to the obesity epidemic among adults and creates a growing health challenge for the next generation.

Figure 8 shows WHO's most recent adult overweight prevalence rates of both sexes of 34 European countries. Bearing in mind the data's limitations, it can be observed that sixteen countries have a prevalence rate equal or higher than 50% - with Germany having the highest rate; sixteen have a rate ranging between 40 and 50%; and only two have a rate between 30 and 40%.

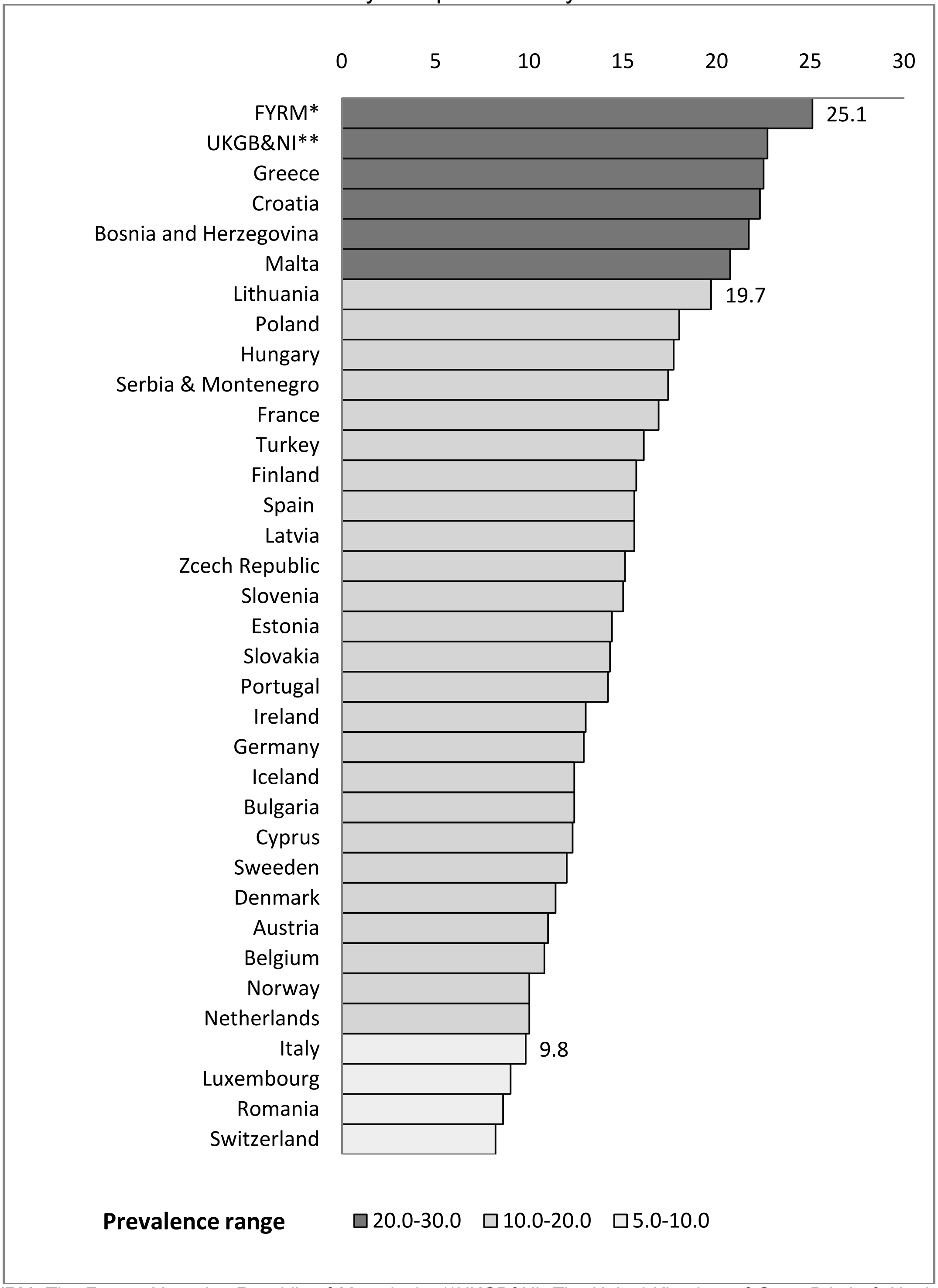
Figure 8. WHO's most recent overweight prevalence (%) in adults aged 20+ years, by European country.



*UKGB&NI: The United Kingdom of Great Britain & Northern Ireland. **FYRM: The Former Yugoslav Republic of Macedonia.
Source: adapted from WHO's data (WHO 2014). Country comparison - BMI adults % overweight (>=25.0), Most recent.
Caveat: The national BMI data displayed in this graphs are empirical and have been verified that they apply internationally recommended BMI cut-off points. However, it is important to note that the data presented are not directly comparable since they vary in terms of sampling procedures, age ranges and the year(s) of data collection.

In addition, Figure 9 shows WHO's most recent adult obesity prevalence rates in 34 European countries. Six countries have a prevalence rate in the range of 20-30%, with the Former Yugoslav Republic of Macedonia taking the lead.

Figure 9. WHO's most recent adult obesity prevalence (%) in adults aged 20+ years, by European country.

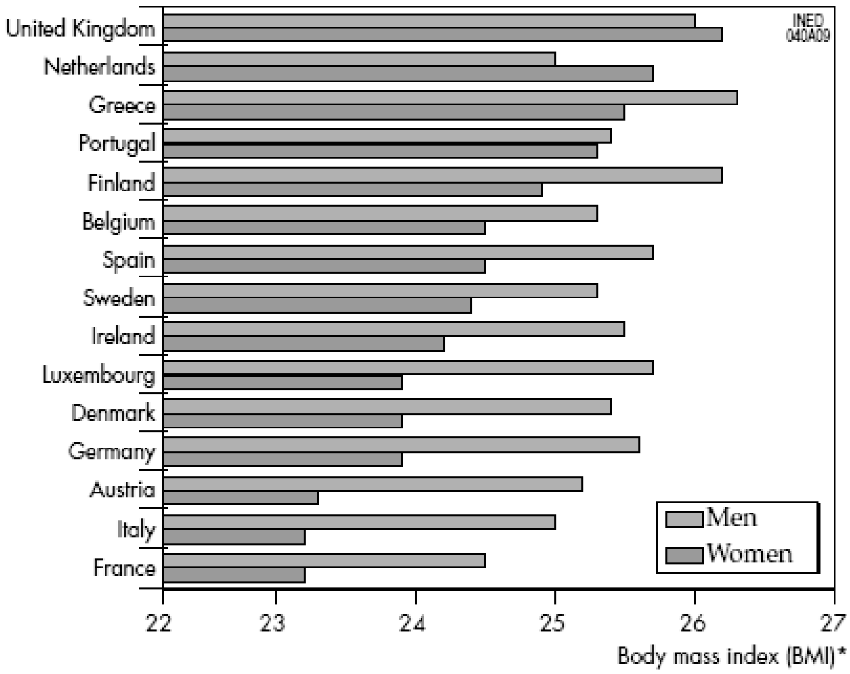


*FYRM: The Former Yugoslav Republic of Macedonia. **UKGB&NI: The United Kingdom of Great Britain & Northern Ireland.
Source: adapted from WHO's data (WHO 2014). Country comparison - BMI adults % obese (>=30.0), Most recent
Caveat: The national BMI data displayed in this graphs are empirical and have been verified that they apply internationally recommended BMI cut-off points. However, it is important to note that the data presented are not directly comparable since they vary in terms of sampling procedures, age ranges and the year(s) of data collection.

According to the IASO/IOTF, in the European Union (EU) 27 member states, approximately 60% of adults and over 20% of school-age children are overweight or obese. This equates to around 260 million adults and over 12 million children being either overweight or obese (IASO/IOTF 2014).

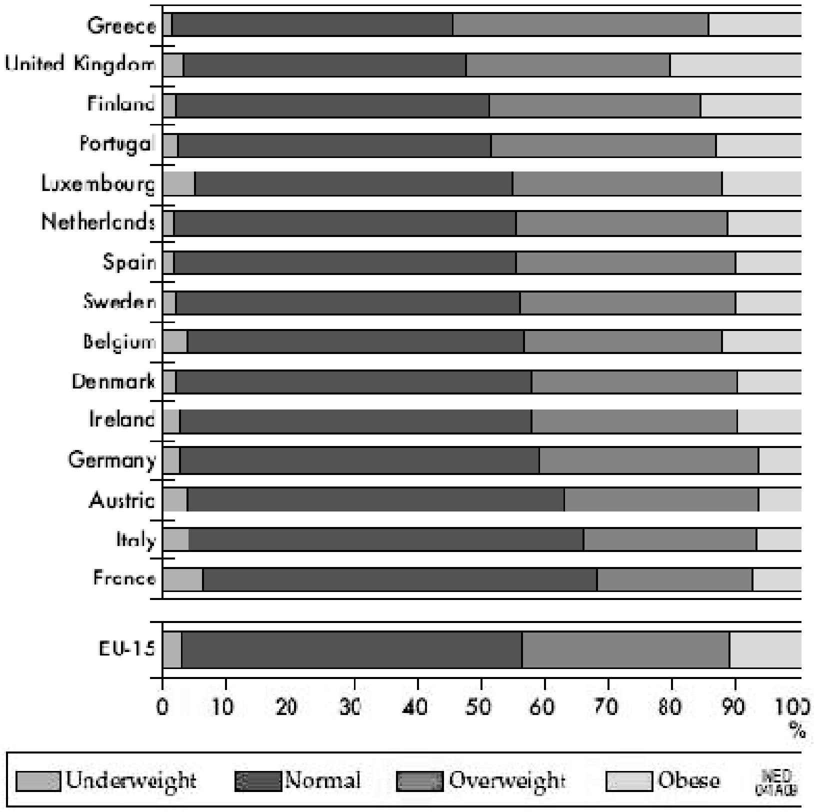
Using data from Eurobarometer 59.0 (European Commission 2003), de Saint Pol reported the male and female mean BMI in 15 European countries (Figure 10), as well as the population breakdown by BMI category in each country (Figure 11) (de Saint Pol 2009). The United Kingdom had the highest female mean BMI, whereas Greece had the highest male mean BMI. Again, Greece and the United Kingdom had the greatest proportion of obesity and overweight.

Figure 10. Mean BMI in Europe by sex.



Source: *de Saint Pol 2009; European Commission 2003: Eurobarometer 59.0.*
Note: mean BMI of European men is higher than that of women, except in the United Kingdom and the Netherlands.

Figure 11. Population breakdown by BMI category in each country (men and women combined).



Source: *de Saint Pol 2009; European Commission 2003: Eurobarometer 59.0.*
Note: The proportion of obese is under-estimated in some countries due to reporting bias.

Spanish data

In Spain, several studies have coincided in that adult, adolescent and child obesity prevalence has also increased in the last decades (Serra-Majem *et al*. 2003; Aranceta-Bartrina *et al.* 2005). They have recognized that the group of children aged between 6 and 13 years and the group of women aged over 45 years are the groups with the highest risk of obesity; moreover, obesity prevalence is higher among males during years of growth and development (Serra-Majem *et al*. 2003; Aranceta-Bartrina *et al.* 2005), while in the over 45-year group it is significantly higher in females (Gutiérrez-Fisac *et al*. 1994; Aranceta-Bartrina *et al.* 2005). In a study in Southern Spain, the authors found that a larger proportion of men were overweight compared to women, but the opposite was found for obesity (Mataix *et al*. 2005). In 2004, the results from the DORICA Study (Aranceta *et al*. 2004) showed that the obesity prevalence of the North-Eastern region of Spain (which includes Catalonia) was 8.5% for men and 13.8% for women, which were the lowest out of the eight regions included in the study (Aranceta-Bartrina *et al.* 2005).

More recently, Gutiérrez-Fisac *et al*. (2011) using data from the ENRICA study[2] (Gutiérrez-Fisac *et al*. 2012), have for the first time reported the prevalence rates of the Spanish adult general and abdominal obesity based on measured weight, height and WC –defining overweight as BMI 25–29.9 kg/m^2, obesity as BMI$\geq$30 kg/m^2 and abdominal obesity as WC >102 cm in men and >88 cm in women. They found that the prevalence of general obesity was 22.9% (24.4% in men and 21.4% in women), and about 36% of adults had abdominal obesity (32% of men and 39% of women). Moreover, the frequencies of general and abdominal obesity increased with age and affected 35% and 62% of persons aged 65+, respectively; while they decreased with increasing educational level (for example, 29% of women with primary education or less had obesity vs. only 11% of those with university studies). As for regional variation, they observed that the prevalence of obesity (age-adjusted) was very high in the Canary Islands and in the south of Spain. In Catalonia, the prevalence of general obesity was slightly higher in men as compared to women (21.8-24.8% vs. 20.1-23.4%), while that of abdominal obesity was much higher in women as compared to men (<25.5 vs. 34.8-38.9%) (Gutiérrez-Fisac *et al*. 2012).

1.1.4 Environmental determinants of overweight and obesity

Obesity and overweight are fundamentally caused by an energy imbalance between calories consumed and calories expended (Hill *et al*. 2012). Globally, there has been an increased intake of energy-dense foods that are high in fat, and an increase in physical inactivity due to the increasingly sedentary nature of many forms of work, changing modes of transportation, and increasing urbanization (Hill *et al*. 2012). The WHO recognizes that changes in dietary and physical activity patterns are often the result of environmental and societal changes associated with development and lack of supportive policies in sectors such as health, agriculture, transport, urban planning, environment, food processing, distribution, marketing and education (WHO 2013).

Excess body weight has been related to a number of socio-demographic, socio-economic and lifestyle/behavioural determinants (Serra-Majem & Bautista-Castaño 2013):

[2] The ENRICA study is a cross-sectional study carried out between June 2008 and October 2010 in 12,883 individuals representative of the non-institutionalized population on Spain aged 18 years and older.

- **Socio-demographic and socio-economic determinants**

  - *Age and gender:* Differences in the distribution of weight indexes according to age and sex have been reported. Almost all studies conducted in adults residing in Spain – including by the ENRICA study (Gutiérrez-Fisac *et al*. 2012), the EnKid (Serra-Majem *et al.* 2003) and in the National Health Study- have reported a higher prevalence of obesity in males as compared to females and this prevalence increases as age advances (Serra-Majem & Bautista-Castaño 2013). Weight indexes and obesity prevalence increase with age in both men and women, reaching a maximum at around 60 years of age (Serra-Majem & Bautista-Castaño 2013). In adults, overweight prevalence increases until the age of 55 in males and until the age of 70 in females (INFITO 2009).

  - *Cultural level:* An inverse relationship has been observed between cultural level and obesity prevalence in most of the epidemiological studies on obesity, so that the lower the educational level, the higher the prevalence of obesity. According to the EnKid study, in children and adolescents, this was particularly important in girls and for the cultural level of the mother (Serra-Majem *et al.* 2003).

  - *Socioeconomic level*: Socioeconomic factors can influence differently in developing as compared to more developed countries. In developed countries, obesity prevalence is generally higher in the lower socioeconomic groups. On the contrary, in less developed countries obesity most frequently affects the highest socioeconomic groups, particularly those who have western lifestyles (Serra-Majem & Bautista-Castaño 2013).

  - *Geographic distribution:* Geographic differences have been observed in obesity prevalence. For example, in different Spanish regions, the highest rates have been observed in the Southern Autonomous Communities, the Canary Islands and the Northwestern region (Serra-Majem & Bautista-Castaño 2013).

- **Lifestyle related factors**

  - *Sedentary habits:* Obesity is more frequent in sedentary persons as compared to those regularly active (Serra-Majem & Bautista 2013).

- *Diet*: Individuals with low fruit and vegetable consumption and high fat intake, especially in saturated fatty acids, have a greater risk of obesity *(*Serra-Majem & Bautista 2013; Gargallo Fernández *et al.* 2012*)*. In some countries, habitual consumption of alcohol and sugary beverages (Serra-Majem & Bautista 2013; Gargallo Fernández *et al.* 2012*)* has also been associated with excess body weight. In Spain, *Gargallo-Fernández 2012 also listed other factors such as: a* high intake of meat and processed meat products might increase weight gain and WC; offering larger portions (which conditions an increase of the individual's caloric intake*)*; the absence of supermarkets with fruit and vegetable availability, or their location at greater distances -in particular from neighborhoods with low socioeconomic levels- which are conditioning factors for a higher population mean BMI; finally, the habitual intake of "fast food" (over once a week), which might contribute to increased energy intake and to weight gain and obesity.

- *Smoking cessation*: Increased BMI has also been associated with having quit smoking in former smokers. Results from a subsample of the NHANES III Study showed an average weight gain due to smoking cessation of 4.4 kg in males and 5 kg in females who had quit smoking within the previous 10 years (Flegal *et al.* 1995).

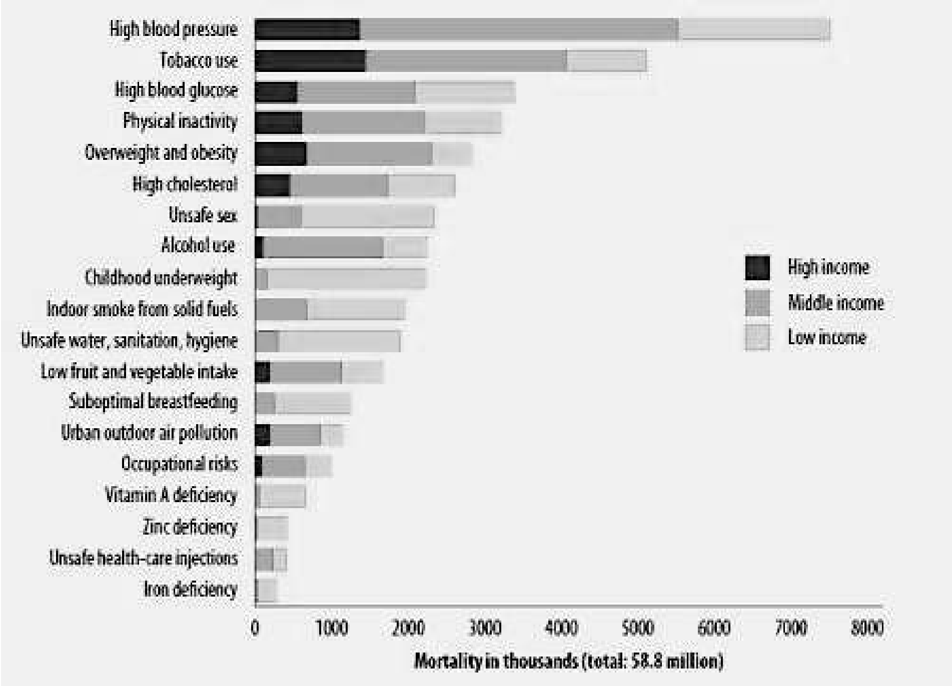
- *Parity*: There is a positive association between the number of children and excess body weight. In general, women tend to increase their usual weight by a certain number of kilograms two years post partum as compared to nulliparous women of the same age group and environment. This positive association was also observed in the DORICA study (Aranceta *et al.* 2004).

1.1.5 Health consequences of overweight and obesity

On death rates

The WHO states that overweight and obesity are the fifth leading risk for global deaths (shown in Figure 12) (WHO GHR Report 2009). The WHO also report that at least 2.8 million adults die each year as a result of being overweight or obese. In addition, 44% of the diabetes burden, 23% of the ischaemic heart disease burden and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity. Moreover, overweight and obesity are linked to more deaths worldwide than underweight. For example, 65% of the world's population live in countries where overweight and obesity kill more people than underweight (this includes all high-income and most middle-income countries) (WHO 2013).

Figure 12. Deaths attributed to 19 leading risk factors, in 2004.



Source: WHO Global Health Risks Report, 2009 (WHO GHR Report 2009).

In addition, obesity shortens life expectancy. As reported in the WHO Global Health Risks (GHR) Report (WHO GHR Report 2009), in 2004, increased BMI alone was estimated to account for 2.8 million deaths, while the combined total with physical inactivity was 6.0 million – surpassing the excess mortality associated with tobacco, and approaching that of high blood pressure, the top risk factor for death (WHO GHR Report 2009).

Moreover, relationships between obesity and health risks vary between populations. For instance, Asians are more susceptible and thus BMI risk thresholds are lower than other populations, with an action point for overweight defined at 23 kg/m^2 (World Obesity 2014).

On non-communicable diseases (NCDs)

An increased BMI is also considered a major risk factor for NCDs. According to the WHO, these include: cardiovascular diseases (mainly heart disease and stroke), which were the leading cause of death in 2008; diabetes; musculoskeletal disorders (especially osteoarthritis); and some cancers (endometrial, breast, and colon). The risk for these NCDs increases with the increase in BMI (WHO 2013). Moreover, in children, obesity is associated with a higher chance of adulthood obesity, disability and premature death. But in addition to increased future risks, obese children experience breathing difficulties, increased risk of fractures, hypertension, early markers of cardiovascular disease, insulin resistance and psychological effects.

On the "double burden" of disease

The WHO informs that many low- and middle-income countries, while they continue to deal with the problems of infectious disease and under-nutrition, they are experiencing a rapid upsurge in non-communicable disease risk factors such as obesity and overweight, particularly in urban settings. It is common to find under-nutrition and obesity coexisting within the same country, the same community and even the same household. The situation is cruder for children in these countries because they are more vulnerable to inadequate pre-natal, infant and young child nutrition. At the same time, their diet is high-fat, high-sugar, high-salt, energy-dense and micronutrient-poor, what makes it lower in cost but also lower in nutrient quality. These dietary patterns in conjunction with lower levels of physical activity result in sharp increases in childhood obesity while under-nutrition issues remain unsolved (WHO 2013).

On the costs of healthcare and social resources

Obesity has substantial direct and indirect costs that put a strain on healthcare and social resources. Some examples are as follows (World Obesity 2014):

- Direct medical costs: include preventative, diagnostic and treatment services related to overweight and associated co-morbidities. Experts have reported that European nations spend 2-8% of their health care budgets on obesity, equating to 0.6% of gross domestic product (GDP) for some (Müller-Riemenschneider *et al.* 2008). Also, in the United States, estimates based on 2008 data indicated that overweight and obesity account for $147 billion in total medical expenditure (Finkelstein *et al.* 2009).

- Indirect costs: costs to society can be much higher, but they are often neglected. They include for example costs related to income lost from decreased productivity, reduced opportunities and restricted activity, illness, absenteeism and premature death. In addition, there are high costs associated with the numerous infrastructure changes that societies must make to support obese people (for example, reinforced beds, operating tables and wheel chairs, enlarged seats in sports-grounds, and modifications to transport safety standards).

Social consequences

Obese individuals commonly suffer from wide-ranging psychological problems that can be potentially serious. They are often stigmatized due to the growing worldwide awareness of obesity, which may have reinforced prejudice against the obese. Depression and low self-esteem can affect an individual's quality of life, mental health, educational achievement and employment prospects. However, the social impact of obesity and its perception are modulated by cultural and ethnic factors. For example, in some parts of the world – such as the Pacific Islands and parts of Africa – obesity may still have historic and cultural connotations associated with power, beauty and affluence (World Obesity 2014).

1.2 Plant food supplements – relevant aspects

The popularity of botanical products is on the rise in Europe, with consumers using them to complement their diets or to maintain health, and products are taken in many different forms (e.g. teas, juices, herbal medicinal products, plant food supplements (PFS). However there is a scarcity of data on the usage of such products at European level.

This section presents a background on some relevant topics related to plant food supplements (PFS) that will provide a context for better understanding the research presented in both Chapters 3 and 4.

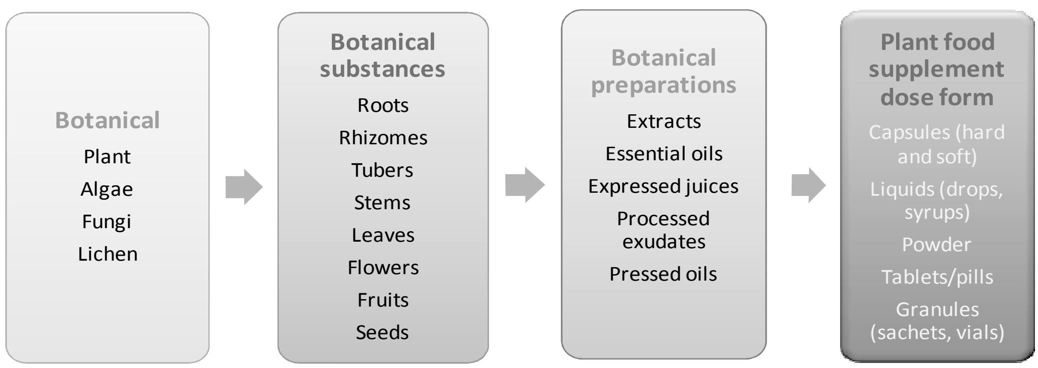
1.2.1 Concepts and definitions to consider when collecting data on PFS consumption

When collecting data on PFS consumption it is essential to have all relevant concepts and definitions harmonized. This section summarises the main concepts and definitions used in the work carried out during the conduction of the PlantLIBRA PFS Consumer Survey 2011-2012.

Origen and definition of a PFS

In order to have a general idea of where PFS derive from, Figure 13 shows a route that botanicals follow to arrive to the dose form of PFS.

Figure 13. From the botanical to the PFS.



The differences between botanicals, botanical substances, botanical preparations and PFS can be derived from the following definitions:

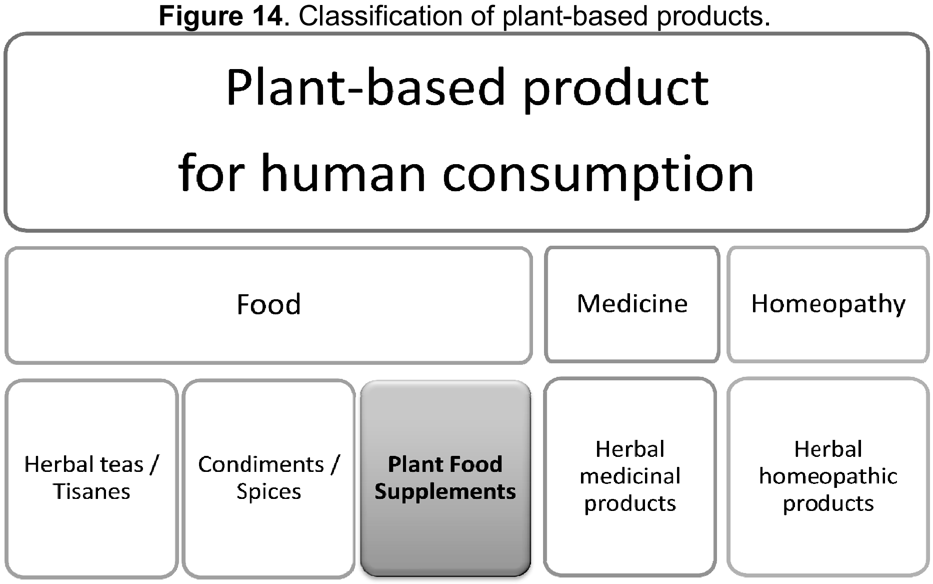
- Botanical: Consists of plants, algae, fungi or lichens that have a nutritional or physiological effect. Botanicals are precisely defined by the botanical scientific name according to the binomial system (genus, species, variety and author).

- Botanical substances*: Derived from botanicals, are mainly whole, fragmented, or broken plants, parts of plants, algae, fungi or lichens in an unprocessed state - usually in dried form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be botanical substances.
*Note: Can also be referred to as "plant parts used" or "plant used portions".

- Botanical preparations: Used in PFS, are obtained by subjecting botanical substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include extracts, essential oils, expressed juice, etc.

Botanical substances and botanical preparations are included in different products, generally designed as plant-based products for human consumption, and further classified as food, medicine or homeopathic product (Figure 14).

Figure 14. Classification of plant-based products.



A "plant-based product" is any product intended for human consumption that has botanical ingredients. This includes herbal teas/tisanes, condiments/spices, PFS, herbal medicinal products and herbal homeopathic products. As these products might be confused with PFS, the definition of each of them as given below:

- Herbal[3] teas/tisanes: Consist of one or more botanical substances intended for oral aqueous preparations by means of decoction, infusion or maceration. Herbal teas are usually supplied in bulk form or in sachets and prepared immediately before use. The term "herbal teas" is also used to designate instant soluble preparations (tisanes) also obtained by means of decoction, infusion or maceration. Usually, infusion is appropriate for leaves, flowers and delicate parts whereas decoction or maceration is appropriate for roots, rhizomes and barks. These preparations are usually consumed as beverages.

- Condiments/spices: Are classified as plants or botanical substances, fresh or dried, whole, fragmented or powdered, for their colour, aroma or flavour characteristics. They are used to prepare food and beverages to incorporate these features so as to make them products more palatable and tasty and thus enhancing their better consumption.

- Plant food supplement: According to the Directive 2002/46/EC (European Parliament & Council 2002), food supplement is defined as "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities". This definition includes the general statement "concentrated sources of nutrients or other substances", which, for the purpose of the PlantLIBRA PFS Consumer Survey was replaced by the specific term "botanical preparations" (the adapted definition is included in Chapter 3).

- Herbal medicinal products (see definition of "herb" in footnote 3): Any product used for a medicinal purpose, exclusively containing one or more herbal substances or one

[3]Definition of "herb": The term "herb" has more than one definition. Botanists describe an herb as a small, seed bearing plant with fleshy, rather than woody, parts (from which we get the term "herbaceous"). According to *The Herb Society of America's New Encyclopaedia of Herbs and Their Uses* (Bown 2001), the term refers to a far wider range of plants. In addition to herbaceous perennials, herbs include trees, shrubs, annuals, vines, and more primitive plants, such as ferns, mosses, algae, lichens, and fungi. They [herbs] are valued for their flavour, fragrance, medicinal and healthful qualities, economic and industrial uses, pesticidal properties, and colouring materials (dyes)."

or more herbal preparations as active ingredients, or one or more such herbal substances in combination with one or more such herbal preparations. These products have two important characteristics: they have a therapeutic effect and need marketing authorisation.

- Homeopathic products (including herbal-based): Are prepared from botanical, zoological o human substances (of natural or synthetic origin), products or preparations called stocks, in accordance with a homeopathic manufacturing procedure. A homeopathic preparation is usually designated by the Latin name of the stock, followed by an indication of the degree of dilution.

Characteristics, composition and classification of PFS

PFS have the following characteristics (illustrated in Figure 15): they are *concentrated sources of botanical preparations*, i.e. they must include botanical preparations, e.g. pressed oil of Evening primrose seed. Moreover, PFS can contain *only botanical(s) or botanical(s) in combination with other ingredients* (see classification in Figure 16, which presents two other important aspects of PFS), e.g. only Evening primrose seed oil or this oil combined with vitamin E. Also, they are *marketed in dose form*, e.g. Evening primrose seed oil marketed as soft capsules. Furthermore, they are *designed to be taken in measured small unit quantities*, i.e. the soft capsules of Evening primrose seed oil will be taken in a recommended dose with a frequency and a duration period. In addition, they are meant to *supplement the normal diet*, e.g. Evening primrose seed oil would be an additional source of essential fatty acids. Lastly, they have *nutritional or physiological effects*, e.g. Evening primrose seed oil can be recommended for its nutritional and/or health benefits.

Figure 15. Characteristics of PFS.

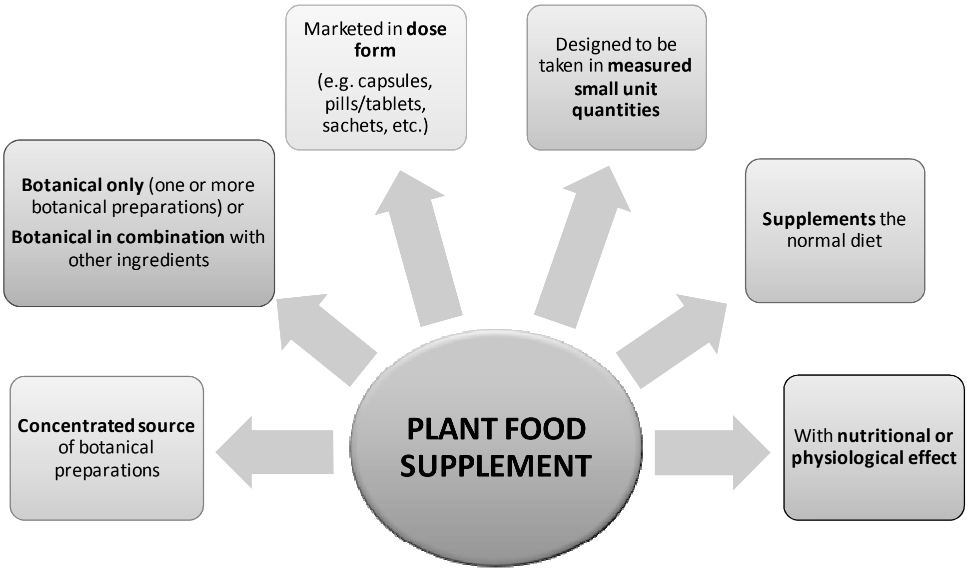
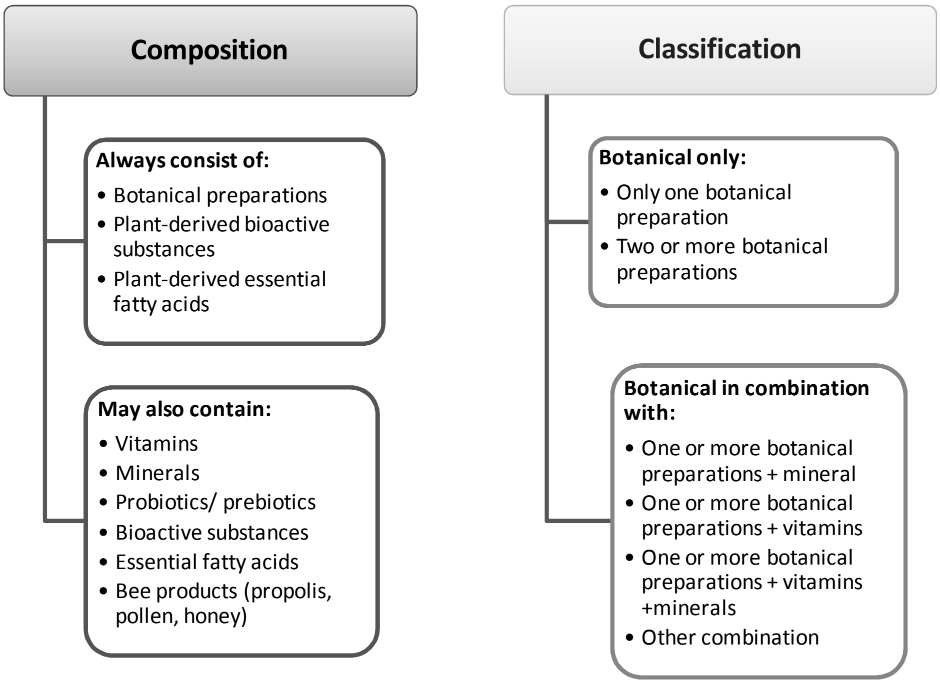


Figure 16. Composition[a] and classification[b] of PFS.

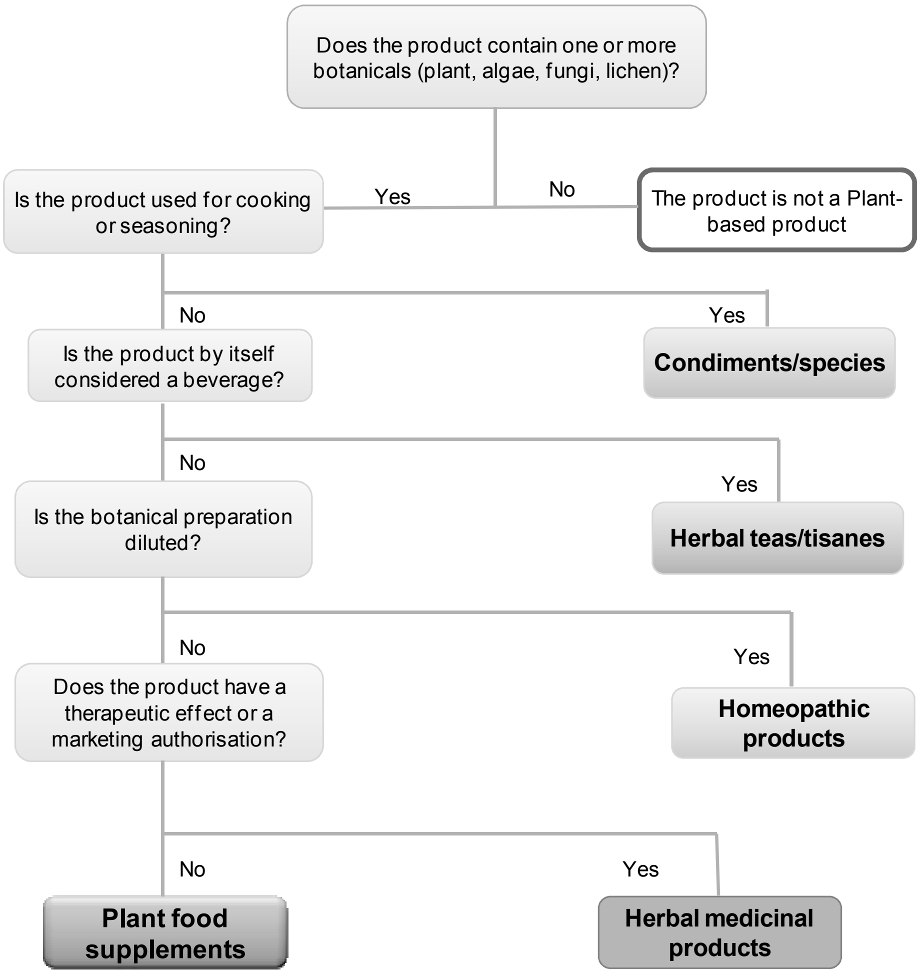


a.PFS are composed of “must” ingredients and “other possible ingredients”; b. PFS can be classified in different ways, according to (among others): the “chemical nature” of their ingredients and their “effect”.

Identification of a PFS in the market

PFS are very specific products and it is not easy to identify them in a market where many other herbal products are used. A decision tree was used -together with all the above information- to train the interviewers during the participant recruitment process of the survey, presented in Figure 17.

Figure 17. Decision tree to identify a PFS.



1.2.2 The PlantLIBRA project and the PlantLIBRA PFS Consumer Survey 2011-2012

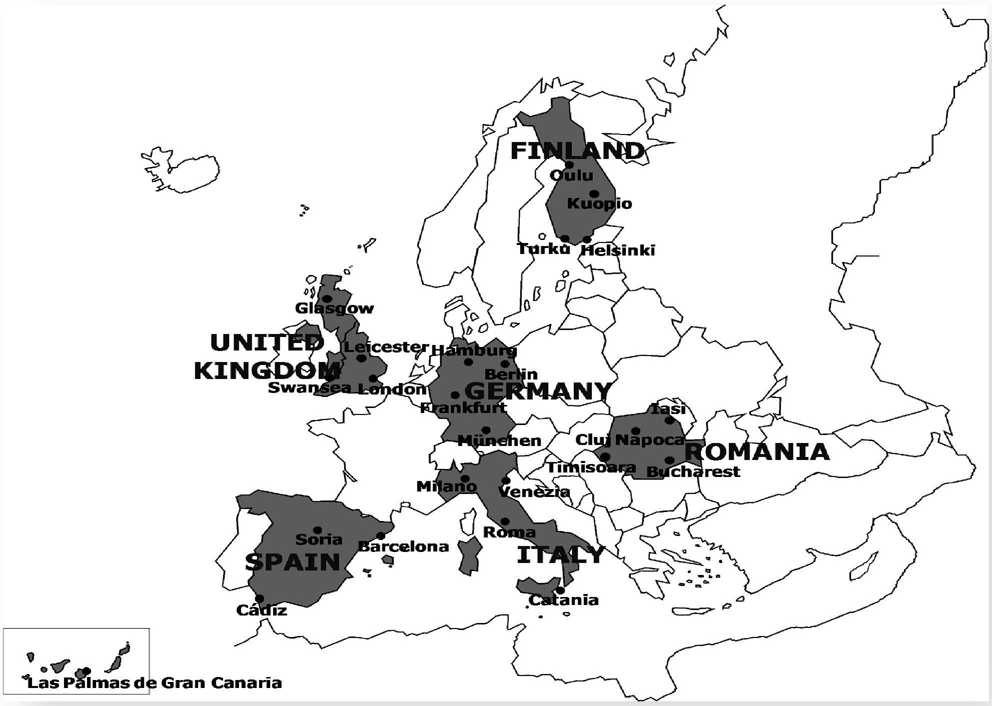
The popularity of botanical products is on the rise in Europe, with consumers using them to complement their diets or to maintain health (e.g. body weight control), and products are taken in many different forms (e.g. teas, juices, herbal medicinal products, PFS). However there is a scarcity of data on the usage of such products at European level.

PlantLIBRA (acronym of "PLANT Food Supplements: Levels of Intake, Benefit and Risk Assessment" - EC contract no. 245199) (www.plantlibra.eu/web) is a four-year research project (2011-2014) co-financed by the EC within the context of the 7th EU Framework Program, that aimed to foster the safe use of food supplements containing plants or botanical preparations, by increasing science-based decision-making by regulators and food chain operators. The project was also structured to develop new methodologies and tools for risk and benefit assessment of PFS.

PlantLIBRA was carried out by an international consortium of 25 partners, including 8 academic centres, 7 public research institutions and national food safety agencies, 6 non-profit bodies or foundations, 3 small- and medium-sized enterprises involved in research and regulation and one private sector enterprise, and spans 4 continents: Europe, Asia (China), South America (Argentina and Brazil) and Africa (South Africa).
The project was organized into 11 work packages (WP). The main activity of WP1 consisted of conducting a survey to assess the consumption of PFS.

The PlantLIBRA PFS Consumer Survey 2011-2012 was conducted by 6 partner centres from the 6 European countries in which it was conducted: Finland, Germany, Italy, Romania, Spain and the United Kingdom. Fieldwork lasted over 15 months, from May 2011 to August 2012. Data were collected from 2359 PFS consumers residing in 24 European cities (4 per country) (Figure 18). A 5-minute questionnaire was used initially to identify consumers of PFS in the previous 12 months (see Annex II). Those considered "eligible consumers" who were also willing to participate completed a 30-minute questionnaire during an interview about their PFS usage. This questionnaire consisted of 58 questions, 20 of which asked about aspects of PFS usage, and 38 asked about socio-demographic, health and lifestyle aspects (see Annex III). Survey results have provided data to assess the socio-demographic profile of PFS users, the usage patterns of these products, the actual products consumed and their botanical ingredients.

Figure 18. Countries and cities participating in the PlantLIBRA PFS Consumer Survey.



It is important to describe how the data have been organized into databases for analysis. In order to properly assess the consumption of PFS in the selected population at the level of all three the product, the botanical and the consumer, three different databases were built and used: 1) the "products-botanicals" database, 2) the "consumer" database, and 3) the merged database of "consumers and products". The first two databases were initially built in each country and then merged into two global ones. The "products-botanicals" database contained collected basic information about the product such as PRODUCT CODE (identification code for each product: it was used as the variable that allowed knowing the main features of the product and the botanicals contained in them, and hence, it was included in both the products-botanicals and the consumer databases), MANUFACTURER CODE (identification code for each producer/laboratory/distributor/brand), FORM (consumption dose form), PRODUCT TYPE (single or multi-botanical), PLANT NUMBER (number of botanicals contained in the product) and PLANT CODE (identification code for each botanical name). The "consumer database" was developed from the survey PFS consumption questionnaire (Annex III). In this database, information was collected on the products consumed (up to a maximum of five products per respondent, as included in the questionnaire. Each of the products consumed was identified with a code number that corresponded to the product code of the products-botanicals database. Lastly, in order to obtain information on the total number of botanicals consumed by each participant in the survey, a new database was generated with all the information contained in the database of products-botanicals and all the information contained in the consumers database. The merging of the two database files was performed using the product code as the connecting link. The aim was to link each product registered as consumed by the survey participants with the data contained in the products-botanicals database, and the product code allowed this matching. With this step, the final database was obtained, which contained in the same one file the respondents data and the data of the products consumed by the respondent. The first generated database file contained a total of 3698 variables, since each of the five (per-consumer) potentially consumed products was assigned the 491 botanical code variables of the products-botanicals database (491x5=2455 variables, plus 1243 variables from the questionnaire=3698). The next step was to generate a new ID code for each of the botanicals and the number of the consumed product (out of the five possible). Since the aim of the study was not to determine the amount of consumed botanicals, but rather whether or not a certain botanical was consumed, all botanical variables for each of the five products were unified in a single variable to identify whether or not the botanical had been consumed regardless of the order number of the product it came from. Thus, the database was reduced to a total of 1937 variables.

Further methodological details are provided in Chapter 3's Materials and Methods section, including the definitions used for a PFS product and of a PFS consumer, the sample distribution, survey instruments and their administration for data collection, and data preparation for analysis.

1.2.3 Regulatory aspects of PFS

Plants or botanicals are being used in many products, including foods, food supplements, medicinal products, cosmetics, biocides, etc. All these different products have their specific legal framework. For example, in the food area, plants are used for seasoning and taste; plants are also used for their health properties, in particular in herbal teas and food supplements; in medicinal products, plants are used for a therapeutic purpose (Larrañaga–Guetaria 2012).

In the EU, it is a general principle that a plant or botanical can be used both in foods/food supplements and in medicinal products, depending on the purpose (health or therapeutic) and in agreement with specific rules regarding safety (Larrañaga–Guetaria 2012). The EU legal system does not set out any kind of authorization procedure centralised at EU level for the use of botanicals and derived preparations in food. Nonetheless, the use of botanicals and derived preparations in food has to comply with the general requirements set out in the Regulation laying down general principles and requirements of food law and creating the European Food Safety Authority (EFSA) (Regulation (EC) No 178/2002). This, among other things, assigns primary legal responsibility for the safety of the products placed on the market to business operators (EFSA 2012). In other words, it is the manufacturer who decides what legal framework to use depending on the use intended for the product, and once this choice is made, he is responsible for applying the relevant legal requirements in a correct way (Larrañaga–Guetaria 2012).

Food supplements are regulated by Directive 2002/46/EC, known as the Food Supplements Directive, and may be marketed within the Community only if they comply with the rules laid down in this directive. (European Parliament & Council 2002) The objective of the document was to harmonize EC rules across Member States, but does not provide for substances other than vitamins and minerals, such as amino and fatty acids, fibers, plants and plant extracts, to be used in food supplements and they continue being regulated by various national decrees, which need to be observed when marketing PFS. These national legislations differ widely. Some Member States have regulated the use of botanicals in detail, based on negative lists of plants the use of which is not allowed and/or positive lists of plants that are accepted to be used. Some apply specific conditions of use (e.g. maximum levels, warning statements) (Larrañaga–Guetaria 2012). But in most Member States, the manufacturer or the person placing the product on the market in the particular territory is obliged to notify the competent authorities of these activities by forwarding a model of the label used. This process is free of charge in some European countries (Vargas-Murga *et al.* 2011). In some case, such information must include specific technical data on the composition and nature of the product. Such information may be assessed by specific national scientific advisory bodies (Larrañaga–Guetaria 2012). Despite this multitude of national rules, a basic European ‘principle of mutual recognition’ applies, by which any product that is lawfully marketed in one Member State can be sold in all 27 Member States. But this principle of mutual recognition is not always accepted and a Member State can restrict the sales of a product in case there would be a risk for consumer health. In such case the burden of proof to demonstrate the safety risk is upon the Member State. Since 2008, Regulation 764/2008 provides for fixed procedures to be followed in such cases. If a Member State consistently refuses to apply mutual recognition, the EC can start infringement procedures against that Member State (Larrañaga–Guetaria 2012).

1.2.4 PFS market data in EC Member States[4]

The European herbal market is growing due to the interest in complementary and alternative healthcare therapies (e.g. acupuncture, ayurvedic medicine, chiropractor, homeopathy, naturopathy, traditional Chinese medicine, yoga), the increase in the elderly population, emerging efficacy studies from plants, including interactions and side effects, as well as consumers awareness about general health and well being.

Member States have a dynamic market for PFS, and in general for herbal products. Recent reports concerning the market data are published by Business Insights (BI), which cover the market for vitamins and minerals, herbs and botanicals, and sports and speciality supplements in Europe and the United States, and by Global Industry Analysts (GIA), which analyzes the worldwide markets for herbal supplements and remedies (Tallon 2011; GIA 2011). According to BI, in the EC, the Nutrition and Health Claims Regulation (EC) Nº 1924/2006 is highly controversial. To date, the EFSA has published 1851 opinions on 4951 submitted claims covering reduction of disease to basic structure function claims. 91% of the claims with published opinions submitted under the 13 route (GIA 2011) have received a negative evaluation by EFSA.

The global herbal supplements and remedies market exhibited robust growth over the decade, with little or apparently no significant decline on account of the worldwide recession and is forecasted to reach US$93.15 billion by the year 2015, according to GIA. The world market in fact, exhibited steady growth for the crisis-ridden period of 2008–2009 and beyond. Recession in the European economy and the increased capital requirements for registration under EC regulation of companies expanded the resources of small companies and provided opportunities for acquisitions in herbal supplement markets. In the United States and Europe, herbal medicines represent a

[4]For completeness purposes, this section has been almost literally taken from Vargas-Murgas *et al.* 2011, publication co-authored by the author of this thesis.

major share of the pharmaceutical market and are included in regular medicinal practice. However, the market is highly regulated and of difficult access, as companies need to pass rigorous tests before mass production.

Europe represents the largest regional market, accounting for the single largest share of the world market. Asia-Pacific and Japan make up the other important markets for herbal supplements on a global basis. In terms of growth rate, the Asia-Pacific market, led largely by China and India, is set to pave the way with the highest Compound Annual Growth Rate (CAGR) of 10.7% through 2015. The market for herbal supplements varies by region based on factors such as consumer awareness, product availability and forms of delivery, product acceptance, and regional regulations (GIA 2011).

A study elaborated by the European Advisory Services (EAS) provide detailed data about the four largest EC Member States, in terms of sales, led by Italy which is closely followed by Germany, the United Kingdom and France (EAS 2007). According to this study, the total size of the EU food supplement market in 2005 was estimated to be around 5 billion euros (retail selling prices). This figure was divided between food supplement products containing vitamins and minerals that had a market share of 50%, and supplements containing other substances with a market share of 43% equivalent to 2.15 billion euros. 75% of the latter value constituted sales of these products in Germany, Italy, France and the United Kingdom. This study also reported that between 1997 and 2005, the growth of the market for food supplements containing other substances ranged between 20% in the United Kingdom to 219% in Poland. The authors stated that the growth projections for this market for the period 2005-2010 indicated a slowdown in growth, and that forecasts for this period varied between the Member States and ranged from 4% to 45%, with an average of 20% to 25% (EC 2008).

Growth projections to 2010 provide an indication of the extent to which previous rapid growth cannot be taken as an indicator of future rapid growth. However, market growth is not expected to reach the levels achieved in the previous decade. The reasons for the market growth decrease might be due to changes of some important economic factors, for example market saturation. Other factors having a strong impact on the growth of the market of food supplements containing other substances might be the notification/authorisation of national requirements, restrictions on distribution channels and the extent to which the national authorities apply mutual recognition (Vargas-Murga *et al.* 2011).

Referring to herbal ingredients, the EAS reported that ginkgo followed by echinacea, garlic and ginseng were the four most commercially important botanicals in the combined markets of seventeen EC Member States, although echinacea and gingko were part of the composition of products registered as medicines. The wide variations in the size of national markets are, in some cases, due to the regulatory origins (Vargas-Murga *et al.* 2011).

1.2.4.1 PFS market trends[5]

A major trend observed in the market is a shift from a single ingredient market to multiple ingredient-based medications for a particular condition. There is also an increased demand for herbal and botanical products in multi formula and combination packed format, as well as for chewable capsules and tablets. Multi-herbs dominate as the largest segment, capturing a significant share of the overall herbal supplements and remedies market worldwide. The segment is also forecasted to surpass other markets, having the fastest compounded growth rate of 9.0% over the analysis period (2000–2006). Soy and specialty herbs are also expected to display strong growth potential in the future (GIA 2011).

Another important trend is seen in the type of consumer. According to the GIA, women, particularly in the middle-aged range, form the major consumer group owing to their growing health-consciousness, increased concern for diet, and enhanced attention towards preventive healthcare. In addition, there is a greater urgency to maintain healthy lifestyles, focusing on alternatives for conventional medicine and general health. Some of the health benefit for which consumers consider herbal and botanical supplements as natural alternatives include: hormone replacement therapy, prostate health, brain health and cognitive function, and joint and connective tissue health (GIA 2011).

GIA reports that the importance of a healthy diet and lifestyle reigns in the minds of the consumer, which is not affected even by the financial crisis witnessed in almost

[5]For completeness purposes, this section has been almost literally taken from Vargas-Murgas *et al.* 2011, publication co-authored by the author of this thesis.

every other product segment worldwide. In fact, the recession may have actually prompted increased preference for dietary supplements. Escalating prices, tighter budgets and high health care and lifestyle costs have actually driven consumers towards the more economical and perceived healthier and safer options of alternative medicine and dietary supplements for relief of physical and mental disorders.

1.2.4.2 PFS distribution channels[6]

Direct sales and consumer sales channels or retailers are the two marketing techniques for PFS used by manufacturers, distributors and importers. Direct sales includes mail order, e-commerce, multilevel marketing and medical & alternative health practitioners, whereas consumer sales address drugstores, health/natural food stores, herbal shops, parapharmacies, pharmacies, supermarkets/mass market, and among others, specialized shops (e.g. gym, hairdresser, healthcare institutions, sporting goods store).

According to GIA, there is an increase in the number of retail outlets along with e-commerce, coupled with efficient support and cooperation of medical and health professionals. Mail order and internet sales are expected to continue growing as a result of the increasing number of internet websites selling PFS.

The common and widely distributed retail channels in the Member States are drugstores, health food stores, herbal shops, pharmacies and supermarkets. Most consumers prefer to buy PFS in herbal shops and pharmacies where they can receive advice on product benefits and dosage.

Multilevel marketing, also known as direct selling, party plans, relationship selling, person-to-person selling, and network marketing constitute another important channel. However, few are used by manufacturers/distributors.

Because consumer demand has increased greatly, larger pharmaceutical companies are entering the market, often by buying supplement firms. As a result, the structure of the market is changing and will continue to change as the PFS market matures.

[6]For completeness purposes, this section has been almost literally taken from Vargas-Murgas *et al.* 2011, publication co-authored by the author of this thesis.

1.2.5 The weight management industry: past, present and future

The IOTF's report "Obesity in Europe 2002" mentioned that in 1995, in Europe, there was an tremendous demand for help amongst the population and their perception that the medical profession was unable or unwilling to respond, which resulted in parallel systems of help being developed, which include: a) unorthodox or private medical groups making unsubstantiated claims of success, b) clubs and commercial slimming groups which charge for the sessions attended, c) food and other companies who market a huge range of "slimming foods" or selective weight loss and diet aids, and d) a remarkable number of magazines giving conflicting advice (IOTF 2002).

The IOTF's report informed that the total spending on the slimming industry in the EU was estimated in the order of at least 15 billion euros per year (and around 1 billion pounds in the United Kingdom) (IOTF 2002). In Spain, the prospective study Delphi reported in 1999 that an estimated 80% of Spaniards who wanted to lose weight spent an average of 60 euros per month in all kinds of treatments, and the total expenditure amounted to 2.05 billion euros (Estudio prospectivo Delphi 1999).

In the United States, sales of weight-loss supplements were estimated to total >1.6 billion dollars in 2005 (Pillitteri *et al.* 2008; NBJ 2006) and the food supplement market increased by 7.5% in 2012 compared with 2011 (reaching 32.5 billion dollars in sales) (Euromonitor International 2014a).

Euromonitor International has recently analysed the future for the weight management industry worldwide (Euromonitor International 2014a). They have stated that the combination of the huge potential customer base and the severity of the excess body weight condition results in an enormous market for weight management and is a key factor for its future growth.

Preliminary Euromonitor International data for the global weight management market showed strong year-over-year gains of 5% in 2013, reaching retail value sales of 14 billion US dollars. They stated that "while growth is projected to continue through 2018, with a 3% CAGR ("compound annual growth rate"), performance varies by region and product type" (Euromonitor 2014b). The Euromonitor International recent report includes projected regional performance data, which is included in Table 6.

Table 6. Projected weight management market growth rates, 2014 through 2018.

Region	Expected growth through 2018 (% CAGR[a])	Comments
Global	3	Growth is projected to continue through 2018, but performance varies by region and product type.
USA	17 (OSP[b]) 15 (OTC[c])	By far the world's largest weight management market, accounting for approximately one-third of sales, which is heavily based on meal replacement slimming products and weight loss supplements. However, the popularity of OSP[b] (i.e. diet patches, creams, extracts, concentrates) and OTC[c] obesity products (e.g. Orlistat) are on the rise.
Asia Pacific	37 (OTC[c])	Historically, this region has been by far the fastest growing weight management market, with 2013 sales up 88% since 2008. The majority of these sales are split between China, Japan, and South Korea. While China and Japan actually posted sales declines since 2008, booming growths in not only South Korea, but also India, Malaysia, Indonesia, and others, were able to offset these drops and boost sales in the region. OTC obesity is mostly absent from this region. However, it was introduced in China in 2011 and is expected to grow at the shown rates through 2018 and achieve sales of US$90 million. On the other hand, slimming teas, for which Asia Pacific currently accounts for two-thirds of global sales, will continue recent declines in the near future.
Eastern Europe	6	Future weight management sales projected to be the fastest growing over the forecast period. Weight loss supplements are the preferred weight management product in this region and are estimated to reach sales of US$514 million in 2018. Much of this growth is attributable to Russia, where product offerings and promotions have developed substantially, led by Poliaris' new brand Reduksin-light.
Latin America	5	Obesity prevalence is growing especially high in this region, most notably in Venezuela. In this country, a slim body is very desirable and associated with success. Weight management is increasingly perceived as an easier way to get slim than changing poor diets and sedentary lifestyles. While meal replacement slimming derives the majority of sales in Venezuela, slimming teas posted year-over-year gains of 94% in 2013.
Western Europe and Australia	1	Lowest growth.
Middle East and Africa	0	Estimated to remain a negligible 1% of the global market.

a. CAGR= Compound annual growth rate; b.OSP="Other slimming products"; c. OTC="Over the counter" products. Source: Adapted from Euromonitor International 2014a.

1.2.6 Classification of botanical products in body weight loss

Weight-loss supplements typically fall into 1 of 4 categories depending on their hypothesized mechanism of action for reducing weight or changing body composition (Manore 2012):

1) Products that block the absorption of fat or carbohydrate, thus decreasing the amount of energy absorbed from food
2) Stimulants that increase metabolism
3) Products hypothesized to alter nutrient partitioning, thus changing body composition by decreasing body fat while increasing lean tissue
4) Products that suppress appetite or increase satiety so that less energy is consumed.

Table 7 briefly covers each category, giving examples of botanical ingredients used in PFS and discussing proposed mechanisms of action and potential side effects described in the literature. Many weight-loss supplements combine multiple ingredients from these categories into one product, which makes testing for efficacy and safety difficult (Manore 2012).

Table 7. A summary of the PFS categories that are hypothesized to achieve weight-loss.

Weight-loss supplement category	Examples of botanical ingredient of supplements	Proposed mechanisms or use	Potential side effects
Absorption blockers	*Phaseolus vulgaris* (common bean)	Alpha-amylase inhibitor: reduces or prevents carbohydrate digestion and absorption.	GI upset, bloating, and gas. No toxicity, based on animal studies (Chokshi 2006).
Stimulants	Caffeine (from coffee seeds, tea leaves, kola nuts, yerba mate, guarana berries)	Increases thermogenesis by inhibiting degradation of cAMP (Diepvens *et al.* 2007). Effects can be potentiated with ephedra or nicotine.	High intakes (≥300 mg/day) can result in insomnia, irritability, heart palpitations, and anxiety.
	Camellia sinensis (green tea (GT) or its extract)	Active ingredients are caffeine and catechins, especially EGCG. May increase thermogenesis, Reduce lipogenesis, and decrease fat absorption or increase fat oxidation.	Generally regarded as safe if taken as tea. GT extracts have been associated with liver damage, especially if ingested on an empty stomach (Sarma *et al.* 2008).
Disruptors of nutrient partitioning or energy	Hydroxycitric acid (HCA), a botanical extract from plants native to India, especially *Garcinia cambogia* (malabar tamarind)	HCA inhibits ATP-citrate-lyase, the enzyme that leaves citrate into oxaloacetate and acetyl-CoA for endogenous fat synthesis (Watson *et al.* 1969; Watson & Lowenstein 1970). HCA may suppress fatty-acid synthesis and food intake while decreasing weight gain.	Numerous safety issues including liver injury. In 2009, the FDA warned consumers to stop using Hydroxycut products that contained HCA (Fong *et al.* 2010).
Appetite suppressants	Soluble fibers (e.g., psyllium, guar gum, beta glucans, or glucomannan)	Soluble fibers hold water and increase satiety and fullness. SCFA can influence production of satiety hormones (Anderson *et al.* 2009; Hosseini *et al.* 2011).	GI upset, bloating, and gas.
	Hoodia gordonii (e.g., Hoodia, Kalahari cactus, Xhoba)	Native plant of the Kalahari Desert in southern Africa associated with reduced hunger. Appetite suppression Attributed to a plant compound called P57, a steroidal alkaloid (Madgula *et al.* 2010).	Safety is unknown. No published studies.

Note. GI=Gastrointestinal; GT=Green tea; EGCG=Epigallocatechin gallate; HCA=Hydroxycitric acid; FDA=Food and Drug Administration; SCFA=short-chain fatty acids. *Source:* Adapted from Manore 2012.

2. Research

2.1 - Chapter 1:

Obesity and overweight trends in Catalonia, Spain (1992-2003): gender and socio-economic determinants

2.1.1 Introduction

Numerous studies have shown that obesity is more frequent in the less socially advantaged population groups, regardless of the variable used to classify socio-economic status (SES); these differences in the prevalence of obesity by SES have been observed both in men and women, but are stronger and more consistent in women (Sobal & Stunkard 1989). The WHO´s MONICA Study showed that the prevalence of obesity is higher among adults and children of low SES (Molarius *et al.* 2000). In Spain, in 1987, a group of researchers found a higher prevalence of obesity among the population of a lower educational level (Gutiérrez-Fisac *et al.* 1994); in the period 1987-1997, the same researchers found a higher obesity prevalence in individuals with elementary education, and that the obesity prevalence proportion associated with elementary education increased in women and decreased in men (Gutiérrez-Fisac *et al.* 2002). Moreover, the SEEDO´97 Study in Spain showed higher obesity rates in men and women with low educational level, and also that older women with low educational level and low income seemed to be the most susceptible group to weight gain (Aranceta *et al.* 2001). Adding to this evidence, a significant inverse relationship between SES and overweight and obesity was found by the AVENA (*Alimentación y Valoración del Estado Nutricional de los Adolescentes Españoles)* Study (Moreno *et al*. 2005), although only in male adolescents.

Overweight and obesity also have a socio-demographic component. In this respect, the SEEDO´97 Study in Spain also showed differences in the distribution of the obesity prevalence by area of residence and geographical zones (Serra-Majem *et al.* 1996).

Other well-known factors that influence the development of obesity are physical inactivity (Jakicic & Otto 2005; Gutiérrez-Fisac *et al.* 2003), over-consumption of energy-dense diets (which has been shown to be associated to low SES) (Rolls *et al*. 2005) and genetic factors (although some authors do not agree to this) (Townsend 2006).

The objective of this chapter is to evaluate the trends (1992-2003) of overweight and obesity prevalences in the 18-75 year-old population of Catalonia, Spain, and the influence of socio-economic and socio-demographic variables on these prevalence trends.

2.1.2 Materials and methods

Sample and subjects

The data analysed belong to the 1992-93 and the 2002-03 cross-sectional Evaluations of the Nutritional Status of the Catalan Population (ENCAT 1992-93 and ENCAT 2002-03) (Serra Majem *et al.* 1996; Serra Majem *et al.*2006). ENCAT is a regional survey carried out periodically by the Department of Health of the Catalan Government and co-ordinated by the Centre for Research on Community Nutrition of the University of Barcelona. The theoretical random sample population and sample size have been described elsewhere (Serra Majem *et al.* 1996; Serra Majem *et al.*2006), comprising the population source of residents in the official census. The samples were stratified according to household and randomized into sub-groupings with municipalities being the primary sample units, and individuals within these municipalities comprising the final sample units. The valid response rate for the first survey was 69% and for the second 65%.

Adults from each representative sample within the age of 18-75 years were included in the analysis of this study (n in ENCAT 1992-93=2248 and n in ENCAT 2002-03=1715).

Data collection procedures and variables of the study

In both surveys, dieticians were trained on standardisation of criteria and methodology before data collection, in order to reduce inter-observer measurement variability. The data were collected from 1992 to 1993 and from 2002 to 2003 through questionnaires and anthropometric measurements during a home interview.

In order to analyse the influence of the socioeconomic variables on the prevalence of overweight and obesity, the following variables were used and rearranged according to the following categories (Aranceta et al. 2001):

1. Socioeconomic level (SEL) (occupation of the subject): a) low: the non-classifiable, army, agricultural sector, service sector and non-qualified labourers; b) medium: qualified labourers, foremen, rest of administrative, commercial and technical staff and medium-level technicians; c) high: high–level technicians, directors/managers, self-employed professionals, business owners or self-employed individuals without staff, business owners or self-employed individuals with staff.

2. Education level of the subject and of the family´s head member (ELS and ELH): a) low: primary school incomplete or illiterate (<6 years at school); b) medium: primary school completed, secondary school or further education (6-12 years of education); c) high: high school, college or university degree (>12 years of education).

The socio-demographic determinants included: 1) gender, 2) age group (18-24 years, 25-44 years, 45-64 years and 65-75 years) and 3) population of residence size (<10,000 inhabitants; 10,000-100,000 inhabitants, and >100,000 inhabitants).

Anthropometric measurements

Body Mass Index*: w*eight and height had been measured with a portable spring scale and a metric tape (Kawe© model). The individuals were measured in standardised conditions, wearing underwear and no shoes. Weight was measured in kilograms, scale measurement error $\pm$100g. Height was measured standing and head in Frankfurt horizontal position, expressed in centimetres, instrumental measurement error $\pm$0.1 cm. BMI was calculated using weight and height and categorized according to WHO criteria (WHO 1998) so that overweight was defined as BMI$\geq$25 to BMI<30 kg/m^2 and obesity as BMI$\geq$30 kg/m^2.

Waist circumference: it was measured with a non-elastic metric tape halfway between the lower border of the ribs and the iliac crest on a horizontal plane. Measurements were recorded to the nearest 0.1 cm and categorized according to WHO criteria, so that men with a WC 94.0–101.9 cm and women with a WC 80.0–87.9 cm were classified as overweight, and men with a WC$\geq$102.0 cm and women with a WC$\geq$88.0 cm were classified as obese (WHO 1998).

Statistical analysis

All analyses were performed with SPSS 12.0. Proportions of overweight and obesity were estimated for each sample separately and stratified by gender and age (to control for its potential confounding effects). The age distribution of the whole Catalan population in 1992-93 was used as a reference. The proportions from the two surveys were compared using the χ^2 statistic test and the means were compared using the *t*-test, considering *p*-values <0.05 for significance.

2.1.3 Results

The sample characteristics of the two surveys are presented in Table 8: the total number of subjects by gender, age group and each socio-economic/socio-demographic variable category.

Table 8. Sample characteristics of the two ENCAT surveys.

	ENCAT 1992-3		ENCAT 2002-3	
Variables	**n**	**%**	**n**	**%**
Gender				
Males	1015	45.2	791	46.1
Females	1233	54.8	924	53.9
Age Group (years)				
18-24	526	23.4	276	16.1
25-44	801	35.6	654	38.1
45-64	668	29.7	557	32.5
65-75	253	11.3	228	13.3
BMI[a] (Kg m $^{-2}$)				
<18.5 (underweight)	37	1.6	33	1.9
18.5-<25 (normal)	1119	49.8	787	45.9
25-<30 (overweight)	807	35.9	624	36.4
>=30 (obese)	285	12.7	271	15.8
WC[b] (cm)				
Normal	1312	59.4	878	52.2
Overweight	484	21.5	349	20.0
Obese	430	19.1	477	27.8
Socioeconomic Level (occupation)				
Low	666	30.5	258	15.2
Medium	964	44.1	627	36.9
High	557	25.5	812	47.8
Education Level Subject				
Low	486	21.6	233	13.6
Medium	1154	51.3	861	50.3
High	608	27.0	618	36.1
Education Level of Family Head				
Low	654	29.1	264	15.5
Medium	1145	50.9	925	54.3
High	449	20.0	513	30.1
Population Size (inhabitants)				
<10,000	294	13.1	379	22.1
10,000 -100,000	604	26.9	541	31.5
>100,000	1350	60.1	795	46.4
TOTAL (n)	2248	100.0	1715	100.0

a. Body Mass Index: according to WHO classification (WHO 1998). b. Waist circumference: according to WHO classification (WHO 1998): normal = <94 cm for males and < 80 cm for females; overweight = 94 - <102 cm for males and 80 - <88 cm for females; obese = $\geq$102 cm for males and $\geq$ 88cm for females. ENCAT – Evaluations of the Nutritional Status in Catalonia.

Table 9 shows the mean, standard deviations and 5th-95th percentiles of BMI and WC by gender and age group. In 2002-03, male mean BMI was higher as compared to 1992-93, although the observed difference was significant only for individuals aged 25-44 years (from 25.2 to 25.9) and 45-64 years (from 26.7 to 27.4), and male mean WC was significantly higher in all age groups; for females the observed decreasing trends in mean BMI in most age groups (except for the youngest) were not significant, while mean WC was significantly higher only in the youngest (from 70.3 to 72.7) and eldest (from 92.2 to 95.3) individuals. These results are shown in Figures 19 and 20, which also show how mean BMI and WC increase as age progresses in both genders. Percentiles 50, 75 and 95 of BMI show increases in males from all age groups and decreases in females (except for the youngest group). As for WC, percentiles 50, 75 and 95 show increases in males and females of all age groups.

Table 9. Mean, standard deviation and percentiles of BMI and WC, by gender, age and survey (ENCAT 1992-93 and ENCAT 2002-03).

Gender	Age (years)	n		Mean			SD		P5		P25		P50		P75		P95	
		1992-1993	2002-2003	1992-1993	2002-2003	*t*-Test[a]	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003
BMI (kg/m^2)																		
Males	18-24	237	116	23.4	24.0	ns*	2.8	3.8	19.2	19.6	21.4	21.4	22.9	23.2	25.2	25.7	28.7	32.5
	25-44	359	309	25.2	25.9	s**	3.1	3.7	20.4	20.3	23.1	23.2	25.0	25.4	27.1	28.1	31.1	33.0
	45-64	312	250	26.7	27.4	s	3.4	3.4	21.4	22.0	24.6	25.5	26.5	27.3	28.6	29.1	31.9	33.2
	65-75	107	116	26.9	27.7	ns	3.5	3.6	21.7	22.6	24.8	24.8	26.2	27.6	29.8	30.4	33.7	33.6
Females	18-24	289	160	22.0	22.1	ns	2.6	3.1	18.5	18.2	20.1	19.9	21.5	21.5	23.6	24.3	26.6	27.8
	25-44	442	345	24.2	23.9	ns	4.1	4.1	19.3	18.9	21.5	20.9	23.5	23.0	26.1	26.1	31.2	31.2
	45-64	356	307	27.7	26.9	ns	4.5	4.7	21.2	19.9	24.7	23.6	27.2	26.3	30.2	29.8	36.0	35.3
	65-75	146	112	28.9	28.3	ns	6.2	4.4	20.5	19.3	25.2	25.8	28.7	28.6	31.4	30.5	38.7	36.3
WC (cm)																		
Males	18-24	237	116	81.8	84.6	s	8.5	12.0	70.0	70.0	76.0	76.9	81.0	83.0	86.5	90.5	97.1	105.5
	25-44	359	309	88.4	91.5	s	9.1	11.1	74.9	74.0	82.0	83.9	88.3	91.0	94.4	97.6	104.1	110.7
	45-64	312	250	95.2	97.7	s	10.5	10.9	79.6	81.3	88.3	92.0	95.0	97.1	102.0	104.3	111.0	117.5
	65-75	107	116	97.0	102.8	s	9.3	10.8	78.7	83.6	91.6	96.0	97.5	102.0	103.2	111.0	111.6	121.4
Females	18-24	289	160	70.3	72.7	s	7.0	7.9	60.6	62.0	66.0	67.0	69.0	71.0	74.0	77.2	84.0	87.0
	25-44	442	345	77.4	78.8	ns	9.9	11.3	64.0	65.0	71.0	70.8	75.5	76.0	83.0	85.0	95.6	100.0
	45-64	356	307	87.1	86.9	ns	10.9	12.8	69.1	68.1	80.0	77.0	85.5	87.0	94.0	95.5	105.9	110.5
	65-75	146	112	92.2	95.3	s	10.0	11.6	76.5	74.0	84.5	88.0	91.8	95.0	99.2	104.9	111.5	114.0

**ns:* non-significant difference (*p*-value $\geq$0.05); ***s*: significant difference (*p*-value <0.05), *a: t*-test used for between-survey comparison of BMI and WC means.). SD = Standard Deviation. P = Percentile; BMI = Body Mass Index. WC= Waist circumference.

Figure 19. Mean BMI by gender, age and survey year
(ENCAT 1992-93 and 2002-03)

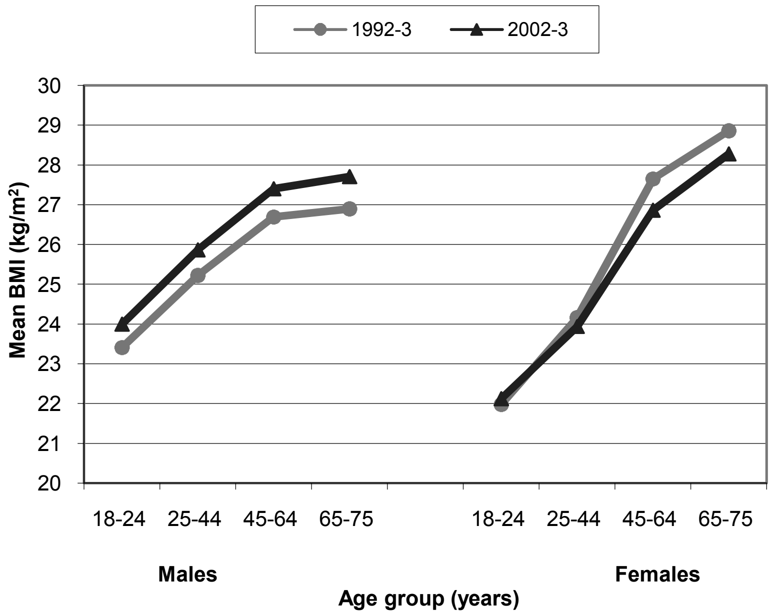


Figure 20. Mean WC by gender, age and survey year
(ENCAT 1992-93 and 2002-03)

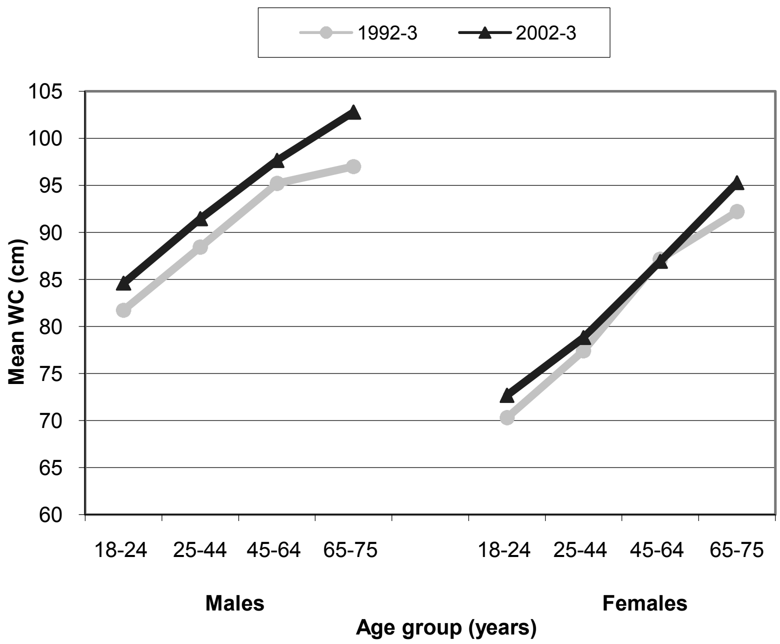


Table 10 shows overall by-gender and by-survey BMI and WC overweight and obesity prevalences; it can be observed that the overall prevalence of BMI obesity has increased significantly only in males (6.7 percentage points, from 9.9 to 16.6%) in the 10-year period, while that of WC obesity has increased in both sexes (11.3 percentage points for males-from 13.1 to 24.4%, and 6.6 for females–from 24.5 to 31.1%). Table 10 also shows BMI and WC overweight and obesity prevalences when age, socioeconomic level, education level and population of residence size are considered.

Table 10. Overweight and obesity prevalence (BMI and WC) by gender, survey year (ENCAT 1992-93 and ENCAT 2002-03), socioeconomic and socio-demographic characteristics.

	BMI Overweight[a]				BMI Obesity[b]				WC Overweight[c]				WC Obesity[d]			
	Males		Females		Males		Females		Males		Females		Males		Females	
Variables	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**	**1992-1993**	**2002-2003**
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Overall prevalence (crude)[e]	44.1	43.7	29.1	30.1	9.9	16.6	15.0	15.2	21.7	23.8	21.8	17.7	13.1	24.4	24.5	31.1
Between-survey comparison	*s**		*ns***		*s*		*ns*		*S*		*s*		*s*		*s*	
Age (years)																
18-24	27.0	19.8	7.3	18.1	2.5	6.9	1.7	1.3	7.7	7.8	7.3	11.9	1.3	6.0	1.7	2.5
25-44	43.2	41.7	26.7	22.9	7.0	13.3	6.6	8.7	18.8	20.3	19.3	15.5	6.2	16.3	14.0	20.7
45-64	56.4	60.0	44.7	37.5	14.7	18.4	27.8	23.8	30.9	31.2	35.8	22.4	24.8	31.2	39.2	43.4
65-75	49.5	37.9	41.8	49.1	21.5	31.0	35.6	31.3	35.5	33.0	23.6	20.0	28.0	49.6	65.3	70.9
Between-survey comparison	*s*		*ns*		*ns*		*ns*		*ns*		*ns*		*s*		*ns*	
Socioeconomic Level (Occupation)																
Low	44.7	44.0	28.6	33.3	11.0	16.5	23.4	19.9	23.5	23.5	23.3	19.0	11.4	25.8	32.0	39.0
Medium	44.8	45.0	30.7	28.2	10.2	16.4	13.3	11.2	22.2	25.1	23.1	16.5	14.2	21.5	22.9	26.0
High	43.0	42.6	25.7	25.2	8.3	16.5	5.8	11.2	18.6	21.9	17.8	17.1	13.3	26.3	15.3	19.3
Within-survey comparison	*ns*	*ns*	*s*	*s*	*ns*	*ns*	*s*	*s*	*ns*	*ns*	*s*	*s*	*ns*	*ns*	*s*	*s*
Between-survey comparison	*s*		*s*		*s*		*ns*		*s*		*s*		*s*		*s*	
Education Level Subject																
Low	53.7	50.5	41.9	45.5	19.1	21.2	32.6	36.6	31.9	28.3	26.7	17.6	21.8	34.3	49.3	69.5
Medium	42.9	43.9	31.4	32.5	9.6	17.6	12.6	15.7	21.5	22.7	24.4	19.7	12.2	25.7	21.8	34.1
High	40.3	41.6	12.3	20.5	4.4	13.6	2.9	5.7	15.5	23.9	11.8	14.9	9.1	19.0	5.9	11.6
Within-survey comparison	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*	*s*	*s*	*s*	*s*	*s*	*s*	*s*	*s*
Between-survey comparison	*s*		*s*		*s*		*s*		*s*		*s*		*s*		*s*	
Education Level Head of Family																
Low	42.1	45.9	32.7	40.1	13.8	17.2	23.9	33.8	22.5	26.2	22.1	16.5	15.2	29.5	35.1	61.9
Medium	46.7	42.9	31.1	31.5	9.6	17.5	13.5	13.4	23.8	22.1	23.9	19.0	12.9	24.9	23.3	30.2
High	41.0	44.8	18.1	22.8	5.1	14.5	5.2	9.2	15.8	25.8	15.4	16.0	10.7	20.4	11.0	17.5
Within-survey comparison	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*
Between-survey comparison	*s*		*s*		*s*		*s*		*s*		*s*		*s*		*s*	
Population Size (inhabitants)																
<10,000	44.3	46.6	32.5	27.8	12.1	16.7	15.6	18.0	21.4	22.1	22.5	12.9	15.7	26.2	31.1	38.6
10,000-100,000	42.2	44.6	28.0	33.6	11.6	15.7	15.2	15.1	20.9	25.0	20.9	20.0	12.7	24.2	25.4	32.1
>100,000	45.0	41.8	28.9	28.8	8.6	17.1	14.8	13.8	22.1	23.7	22.0	18.4	12.6	23.7	22.7	26.8
Within-survey comparison	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*s*	*ns*	*ns*	*ns*	*s*
Between-survey comparison	*ns*		*ns*		*ns*		*ns*		*ns*		*s*		*ns*		*s*	

s*: X^2 test - significant difference ($p<0.05$).*ns*: X^2 test - non-significant difference. a.BMI 25-<30 kg/m^2; b. BMI $\geq$30 kg/m^2; c. WC 94-<102 cm for males and 80-<88 cm for females; d. WC$\geq$102 cm for males and $\geq$ 88 cm for females - (a-d) according to WHO classification (1998). e. See Table 11 for adjusted prevalences.

When considering the variable “age”, Table 10 shows that in ENCAT 1992-93, the highest prevalence of BMI overweight was found in both males and females aged 45-64 years, which was also the case for female but not male WC overweight; while in ENCAT 2002-03, only an increase in female BMI overweight and male WC overweight were observed with progressing age. Regarding obesity, both surveys show an increase in the prevalence of BMI and WC obesity with progressing age in both sexes (note the high prevalence of WC obesity among the eldest men and women in 2002-03, 49.6 and 70.9% respectively). The between-survey comparison shows significant changes only in male BMI overweight and male WC obesity rates, showing alarming increases in the latter rates (i.e. from 1.3 to 6.0% in the 18-24 year-old group).

Regarding the variable “socioeconomic level” (SEL), the differences observed in BMI and WC overweight and obesity prevalences of the different SEL groups were significant only in females of both surveys, WC obesity being highest in the low SEL group (Table 10). In ENCAT 1992-93, SEL was inversely related to the prevalence of BMI obesity, but only significantly in females; this inverse relationship was not observed among SEL groups in ENCAT 2002-03. WC obesity was only inversely related with SEL in females of both surveys and the differences among SEL groups were significant (Table 10). The between-survey comparison shows significant increases in male BMI and WC obesity (from 8.3 to 16.5% and from 13.3 to 26.3%) and female WC obesity (from 15.3 to 19.3%).

With regard to the variable “education level of the subjects” (ELS), in ENCAT 2002-03, Table 10 shows an inverse relationship with BMI overweight and obesity prevalence, but with differences among ELS groups only significant in females (note a female BMI obesity prevalence of 36.6% in the low ELS group); this inverse relationship is observed between ELS and male and female WC obesity but not WC overweight (note the high male and female WC obesity rates in the lowest ELS group, 34.3 and 69.5% respectively). The between-survey comparison revealed significant differences in both BMI and WC overweight and obesity for both genders. It is worth noticing that while male and female WC overweight seem to have increased among the highest ELS group (from 15.5 to 23.9% and from 11.8 to 14.9% respectively), female WC obesity prevalence in the lowest ELS group increased by 20 percentage points (from 49.3 to 69.5%).

The variable “education level of the family head member” (ELH), showed in ENCAT 2002-03 a significant inverse relationship with BMI overweight, BMI obesity and WC obesity in females (Table 10). Females whose family head member had a medium education level presented the highest WC overweight prevalence compared to females whose family head member had a low or high ELH (23.9% in 1992-93 and 19.0% in 2002-03). The between-survey comparison revealed significant differences in both BMI and WC overweight and obesity for both genders. Male and female BMI overweight, male and female BMI obesity, male WC overweight and male and female WC obesity rates have increased in the low and high ELH groups, while in the medium ELH group the increase was only observed in male BMI overweight (from 9.6 to 17.5%) and male and female WC obesity (from 12.9 to 24.9% and from 23.3 to 30.2% respectively). The difference of 27 percentage points in female WC obesity prevalence in the low ELH group is worth noticing (from 35.1 in ENCAT 1992-93 to 61.9% in ENCAT 2002-03).

Regarding “population of residence size”, only ENCAT 2002-03 differences observed in female WC overweight and obesity were significant (“within-survey comparison”, Table 10). The between-survey comparison showed significant differences in all prevalences except for males BMI andWC obesity; it is worth mentioning that, in the <10,000 inhabitants group, while female BMI and WC overweight rates decreased (from 32.5 to 27.8% and from 22.5 to 12.9%, respectively), female BMI and WC obesity rates increased (from 15.6 to 18.0 and from 31.1 to 38.6%, respectively).

Table 11 shows how the ENCAT 2002-03 BMI and WC overweight and obesity prevalences change when adjusting by the ENCAT 1992-93 SEL, ELS, ELH and population of residence size distributions. It is apparent that male and female BMI obesity increases to its highest when standardised by the ENCAT 1992-93 ELS and population size (from 16.6 to 17.8% and from 15.2 to 19.6%, respectively), while male and female WC obesity increases to its highest when standardised by the ENCAT 1992-93 ELS (from 24.4 to 26.7% and from 31.1 to 39.2%, respectively). Male and female BMI and WC obesity decreased when adjusted by the ENCAT 1992-93 SEL distribution.

Table 11. Overall crude and adjusted overweight and obesity prevalences (BMI and WC), by gender and survey year (ENCAT 1992-93 and ENCAT 2002-03).

	BMI Overweight[a]				BMI Obesity[b]				WC Overweight[a]				WC Obesity[b]			
	Males		Females		Males		Females		Males		Females		Males		Females	
	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003	1992-1993	2002-2003
Variables	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Overall crude prevalence	44.1	43.7	29.1	30.1	9.9	16.6	15.0	15.2	21.7	23.8	21.8	17.7	13.1	24.4	24.5	31.1
2002-3 prevalence standardised by 1992-3 SEL[c] distribution (SR[d])	44.1	44.1	29.1	29.4	9.9	16.5	15.0	13.9	21.7	23.9	21.8	17.5	13.1	24.1	24.5	28.3
2002-3 prevalence standardised by 1992-3 ELS[e] distribution (SR)	44.1	45.4	29.1	33.4	9.9	17.8	15.0	19.6	21.7	24.7	21.8	17.9	13.1	26.7	24.5	39.2
2002-3 prevalence standardised by 1992-3 ELH[f] distribution (SR)	44.1	44.3	29.1	31.9	9.9	16.7	15.0	18.6	21.7	24.4	21.8	17.5	13.1	25.2	24.5	36.8
2002-3 prevalence standardised by 1992-3 Pop. Size distribution (SR)	44.1	45.4	29.1	33.4	9.9	17.8	15.0	19.6	21.7	23.7	21.8	17.4	13.1	25.0	24.5	33.0

a. BMI 25 to <30 Kg/m^2 and WC 94 to <102 cm for males and 80 to <88 cm for females, according to WHO classification (1998).
b. BMI $\geq$30 Kg/m and WC$\geq$102 cm for males and $\geq$ 88 cm for females, according to WHO classification (1998).
c. SEL: Socioeconomic Level.
d. SR: Standardised Rate.
e. ELS: Education level of the subjects.
f. ELH: education level of the family head member.

2.1.4 Discussion

The WHO recognises that the main limiting factors when comparing epidemiological studies on the prevalence of overweight and obesity are: the different criteria to define the cut-offs; the different age groups considered; the time interval for collection of data; and studies comparison based on reported weight and height (WHO 1998). This study is based on the 1992-93 and 2002-03 ENCAT surveys, which were carried out on representative random samples of the Catalan population. Both surveys used the same anthropometric measurement procedures (weight, height and WC were measured instead of reported) and socioeconomic factors, and allow for comparison of the same age groups (18-75 years).

The WHO has recommended BMI as a good index of total overweight and obesity (WHO 1998), although it gives no information about body fat distribution, while WC reflects abdominal visceral fat distribution. Nevertheless, the two measures are highly correlated (Sarlio-Lähteenkorva *et al.* 2006). It has been shown that changes in WC accompany changes in cardiovascular risk factors especially in the elderly (Turcato *et al.* 2000). Research has also shown that WC can also predict morbidity and mortality, considering it a better measure of obesity than BMI, since it is a simple and easy measurement (Lean *et al.* 1998); WC is even more strongly associated with metabolic abnormalities and health-care costs than BMI (Sarlio-Lähteenkorva *et al.* 2006). A single WC measurement has been suggested to be used to identify individuals who should seek and be offered weight management (Lean *et al*. 1995). We have used both BMI and WC measures to define total and central overweight and obesity in order to have a more complete overall picture of the problem in the Catalan population.

This study has shown that in Catalonia, in 2002-03, mean BMI in males was higher than in 1992-93, and that of females was lower (except for the youngest group); on the other hand, overall prevalence of BMI overweight and obesity was 43.7% and 16.6% respectively in males, and 30.1% and 15.2% respectively in females. When comparing these figures with those of the 2002 IOTF report for Spain (1998-2000), we observe that overweight was lower in Catalonia in both genders (in Spain 48% for males and 40% for females), while obesity was higher for Catalan males and females (in Spain 12% and 15% respectively) (IOTF, EASO 2002). Therefore, in terms of gender, this study shows that overweight and obesity are more prevalent in men (obesity was more prevalent in women thirteen years ago, but male obesity has caught up and overcome the female prevalence). These findings are in agreement with other literature available from developed countries, which suggests that women hold a more negative attitude towards obesity than men and they are also more heavily influenced by the public negative view towards obesity, thus spending more time, effort and money on the ideal thinner shape (Manios *et al*. 2005).

Regarding WC overweight and obesity prevalences, this study has shown that in ENCAT 2002-03, mean WC was higher in males and females as compared to ENCAT 1992-93 (except for the female group aged 45-64 years). In men, overall WC overweight increased (from 21.7% in 1992-93 to 23.8% in 2002-03), as well as overall WC obesity (from 13.1 to 24.4%). In women, overall WC overweight decreased (from 21.8 to 17.7%), while overall WC obesity increased (from 24.5 to 31.1%). In other words, our results on BMI and WC overweight and obesity suggest that Catalan men are getting bigger overall and also around specifically the waist, while Catalan women are getting smaller overall but with bigger waistlines. They also show that WC obesity is increasing more rapidly than BMI and, while BMI obesity is more prevalent among men, WC obesity is more prevalent among women. These findings agree with those of several recent studies carried out in Northern Europe (Sarlio-Lähteenkorva *et al.* 2006; Chen & Tunstall-Pedoe 2005).

There are few studies that examine the possible relationship of SES and overweight and obesity prevalence, and even fewer for the actual distribution of its prevalence into the SES groups (Sarlio-Lähteenkorva *et al.* 2006; Manios *et al*. 2005; Choiniere *et al.* 2000). Although comparisons are not directly possible, there are three studies that show that obesity rates have been increasing for decades and are in line with our findings in that the prevalence of obesity is higher for the lower SES groups (two of these studies use education (Berkman & Breslow 1983; Lynch *et al.* 1997) and one uses income (Choiniere *et al.* 2000) and for men. Data from the ENCAT 2002-03 survey showed an increasing trend in the prevalence of BMI obesity in all male SEL (using occupation) groups as compared to ENCAT 1992-93, whereas female BMI obesity prevalence only increased in the high SEL group (although not significantly). The analysis showed that SEL had no influence on male BMI overweight or obesity prevalence, and that it only had an influence on BMI overweight and obesity prevalence among the oldest females (45-64 years and 65-75 year-olds), showing an inverse relationship (this further stratification by age group is not shown in the results). Referring to WC, in the ten-year period, only female WC overweight and obesity changed due to SEL, overweight decreased (being highest in the lowest SEL but no inverse relationship was observed) and obesity increased (highest in the lowest SEL, showing an inverse relationship). These findings are in agreement with numerous studies carried out in developed countries by which, overall, the prevalence of obesity is higher in lower SEL groups (Aranceta et al. 2001; Sarlio-Lähteenkorva *et al.* 2006; Stam-Moraga *et al.* 1999). In developing countries the problem has been shown to be more prevalent among the highest SEL groups, some showing the inverse relationship between overweight/obesity and household amenities in both genders and occupational level in men (Fezeu *et al.* 2006).

Studies using the Spanish population have shown that the prevalence of obesity is higher among women and increases with age, particularly in the least educated female subgroups (Aranceta et al. 2001; Gutiérrez-Fisac *et al.* 1994), results that agree with the findings of the present study. The further stratification of each education level by age group (not shown in the results), revealed different prevalences from the overall male and female BMI obesity prevalences probably because the least educated people were mostly the older age group with a higher obesity prevalence, which agrees with findings from the SEEDO´97 Study (Aranceta *et al.* 2001). Regarding WC, we have shown that overweight basically increased in the male and female highest ELS groups, while obesity increased in all ELS groups, being highest in the lowest ELS one (inverse relationship) and most prevalent among the females of this group (reaching an alarming prevalence of 69.5%), and affecting more prominently the 45-64 year-olds (again probably because the least educated people were mostly the older age group with a higher WC obesity prevalence–analysis not shown). These results coincide with those obtained in recent studies (Molarius et al. 2000; Chen & Tunstall-Pedoe 2005; Gutiérrez-Fisac *et al.* 2004), in particular, a study carried out in Spain which showed an even higher prevalence of WC obesity in non-educated elderly females (80.9%) (Gutiérrez-Fisac *et al.* 2004).

With regard to the influence of the area of residence (population size) on excess body weight, no significant differences were found for BMI prevalences in the 10-year period, in the 10-year period, significant differences were found for BMI overweight in both sexes and for female BMI obesity; the differences were also significant for WC male and female overweight and female WC obesity. Females living in the smallest communities showed a decrease in BMI and WC overweight..However, this decrease was probably at the expense of an increase in the female WC obesity. Studies carried out on the Spanish population (Aranceta *et al.* 1998; Aranceta *et al.* 2001) disagree with our BMI findings by not showing significant differences on overweight and obesity when stratifying by population size, but no comparable results are available for WC prevalences.

Finally, SES has been found to be associated with dietary patterns and physical activity (Aranceta *et al.* 1998; Stam-Moraga *et al.* 1999; Manios *et al.* 2005; Proper *et al*. 2007). For example, more disadvantaged population groups generally have a poorer-quality diet (e.g. higher fat intake and lower vegetable consumption) than higher SES groups, which may partly explain the inverse association between SES and obesity demonstrated in some studies (Manios *et al.* 2005; Proper *et al*. 2007). Other studies have evaluated how money expenditure on food can assist in the achievement of a healthy diet (Manios *et al.* 2005; Drenowski & Specter 2004). The inverse relationship between energy density and energy cost suggests that "obesity-promoting" foods are simply those that offer the most dietary energy at the lowest cost. The relative cost also has been taken into account, which increases even further the cost of the healthy diet for the low-income families (Manios *et al.* 2005). The present study has not considered diet, physical activity, income (at least not directly), expenditure on food or food costs in its analysis (which was merely descriptive and far from suggesting causality due to the cross-sectional nature of the data;, therefore, the authors recognize the need for a further and more robust analysis that involves all these lifestyle variables known to affect the relationship between prevalence of excess body weight and SES. In addition, self-reported occupation and education level may be over or under estimated. However, this probably has not significantly modified the classification of the participants into the three SES groups. Moreover, this study has not adjusted WC for BMI, which should be done due to the influence a high BMI can have on a high WC (Sarlio-Lähteenkorva *et al.* 2006). In spite of the mentioned limitations, we believe that our findings contribute to the evidence needed to guide public health policy makers in the design and implementation of preventive campaigns against the increasing trends of overweight and obesity, paying special attention to males and low SEL and education level groups, and small population of residence size (for male overweight and female obesity).

2.3.4.1 Updating note (not included in the *Public Health Nutrition* publication)

Main results showed that SES variables had an influence on BMI and WC overweight and obesity rates mainly on females. WC obesity was only inversely related with SES in females (both ENCAT surveys) and the differences among SES groups were significant. Moreover, female WC obesity in the lowest education level group increased by 20 percentage points in 10 years. We concluded that Catalan males were getting bigger overall and around the waistline, while Catalan females (over 45 years) were getting thinner overall but with bigger waistlines -and more so in the lower SES level groups.

Although these results are significantly important in terms of public health, the data were obtained one and two decades ago (1992-93 and 2002-03 respectively) and so I feel that the discussion included in their *Public Health Nutrition* publication (2006-07) needs updating and contrasting with more recent data. In this respect, it has to be said that unfortunately, recent studies such as the ENRICA study (Gutiérrez-Fisac *et al*. 2012) have shown that chapter 1's findings still prevail almost a decade later, with significant differences between sexes in Spain overall (higher overweight rates in men and higher obesity rates in women); in Spanish women overall, with obesity decreasing as education level increases, in overall Spain; and with abdominal obesity being much higher in women as compared to men in Catalonia. Table 12 compares the prevalence rates of general and central obesity in the Catalan adult population of three cross-sectional surveys: the ENCAT 1992, ENCAT 2003 and the ENRICA 2011 study. Disregarding the different methodologies used in ENCATs and ENRICA an the fact that rates are not directly comparable, we can observe an increasing trend for both general and central prevalence rates over the years. But most importantly, it can be observed that, while general obesity rates are increasing at a similar pace among men and women, central obesity rates among women are -in all three surveys- consistently higher than men's rates, getting close to the 40% in the most recent study.

Table 12. Comparison of general and abdominal obesity prevalence rates from 3 surveys conducted in the population of Catalonia.

	ENCAT 1992 (%)	**ENCAT 2003 (%)**	**ENRICA 2011[a] (%)**
General obesity			
Men (BMI$\geq$30 kg/m^2)	9.9	16.6	21.8-24.8
Women (BMI$\geq$30 kg/m^2)	15.0	15.2	20.1-23.4
Abdominal obesity			
Men (WC>102 cm)	13.1	24.4	25.5
Women (WC>88 cm)	24.5	31.1	34.5-38.9

a. Source of data: Gutiérrez-Fisac *et al*. 2012.

2.2 - Chapter 2:

Trends in the association between smoking history and general/central obesity in Catalonia (1992-2003), Spain

2.2.1 Introduction

In developed countries, the most important modifiable factors recognised as responsible for excess mortality and morbidity at the population level are tobacco smoking and obesity (Adami & Trichopoulos 2003; Poulter 2003; Bamia *et al.* 2004). Smoking cessation has been associated with increased risk of weight gain (Caan *et al*. 1996; Xu *et al.* 2007). In addition, it has been suggested that current smoking — particularly of high intensity — may increase insulin resistance and may thus be associated with central fat accumulation (Clair *et al.* 2011), which could increase the risk of diabetes and metabolic syndrome and, hence, the risk of cardiovascular disease (Chiolero *et al.* 2008; Pisinger 2009). Thus in addition to more direct pathways, smoking may also contribute to morbidity and mortality indirectly through an influence on obesity, particularly as numerous studies suggest that central fatness is a more important determinant of disease risk than is generalized obesity (Wei *et al.* 1997; Folsom *et al.* 1993; Pi-Sunyer 2000). Individuals with elevated WC, a marker of abdominal fat accumulation, appear to have higher risks of developing diabetes (Seidell *et al.* 1997), hypertension (Beegom *et al.* 1995) and CVD (Dipietro *et al.* 1999) than those with elevated BMI alone.

Although the relationship between overweight/obesity and smoking is receiving increasing attention (Chiolero *et al.* 2008; Williamson *et al*. 1991; Flegal 2007; Pisinger & Jørgensen 2007), a greater pool of evidence is needed, especially on the relationships between central fatness and smoking. In particular, it is crucial to explore both the emerging evidence that central fatness and current heavy smoking may co-occur, and attenuation of the relationships between weight status and smoking cessation over the longer term. Moreover, given that the studies where there was not an increased risk of overweight or obesity associated with smoking were conducted fairly recently (Xu *et al.* 2007; Clair *et al.* 2011; John *et al.* 2005), it is important to assess whether and how the rising prevalence of obesity in the general population may influence relationships observed between smoking and body weight.

The aim of this paper is to contribute to the understanding of these issues by examining the relationships between past and current tobacco use and both BMI and WC in a Mediterranean area with high smoking (Jané *et al.* 2002) and obesity rates (Garcia-Alvarez *et al.* 2007; Shröder *et al.* 2007). Our objectives are: 1) to examine 10-year prevalence trends in observed general/central fatness patterns among subjects of different smoking habits; 2) to examine the association between smoking and both general/central fatness after adjusting for possible confounders; and 3) to understand how these relationships change with temporal trends in the prevalence of both obesity and smoking.

2.2.2 Materials and methods

Conduction of the surveys

The Evaluation of the Nutritional Status of the Catalan Population (ENCAT) is a regional survey carried out every ten years by the Department of Health of the Catalan Government and co-ordinated by the FIN (formerly the CRENC). So far, two surveys have been conducted: the ENCAT 1992-1993 and the ENCAT 2002-2003. ENCAT's random sample population consisted of civilian non-institutionalized individuals aged 6 to 75, living in 82 Catalan municipalities of different sizes (ENCAT 1992-1993 with an N=2,757 and ENCAT 2002-2003 with an N=2,160). The sample was weighted to reflect the population distribution in the official census. The response rate for the first survey was 68.9% and for the second 66.0%. Further details on sampling have been described elsewhere (Serra Majem *et al*. 1996; Serra Majem *et al*. 2007; Ribas-Barba *et al*. 2007).

Recruitment of each of the selected sample populations was carried out using the IDESCAT census (IDESCAT: Population and Housing Censuses). Selected individuals who were going to be interviewed received an information letter from the Department of Health announcing the study and asking for their collaboration. When fieldwork started, the interviewer visited the home of the person selected and requested his/her participation; if the person could not be contacted (at least three attempts at different times in the day), the person was replaced with a substitute of the same age group and sex.

Study sample population

Data used in the current paper consisted of 1,242 individuals from the ENCAT 1992-1993 and of 1,223 individuals from the ENCAT 2002-2003 - all aged 25-60 years. However, analysis included all subjects aged 25-60 years with available data on anthropometric measures and smoking history, i.e. from ENCAT 1992-1993, a total of 1,071 subjects, 482 men (45.0% of the sample) and 589 women (55.0%), and from

ENCAT 2002-2003, a total of 1,128 subjects, 515 men (45.7%) and 613 women (54.3%). Mean age, the gender distribution, and level of education did not differ between the analysis sample and the full sample aged 25-60 years ($p>0.05$ for all three variables) in either of the surveys.

Data collection

All data were collected by trained dietician-interviewers using standardized questionnaires and anthropometric measurements (weight, height and WC) during a home interview. Weight and height were measured with a portable spring scale and a metric tape (Kawer model). The individuals were measured in standardised conditions, wearing underwear and no shoes. Weight was measured in kilograms, scale measurement error 6100 g. Height was measured standing and head in the Frankfurt horizontal position, expressed in centimetres, instrumental measurement error 60.1 cm. Waist circumference was measured with a non-elastic metric tape halfway between the lower border of the ribs and the iliac crest on a horizontal plane; measurements were recorded to the nearest 0.1 cm.

In ENCAT 1992-1993, a first 24-hour dietary recall was conducted in a warm season – May/July - and a second one in a cold season - November/December. In 2002-2003, the 24-hour dietary recalls were conducted throughout the entire year; in both surveys the dietary recalls were conducted on different days of the week including weekend days. Food data was coded into groups and quantified by the interviewers and supervised by two dieticians. The food composition tables used were the Spanish Food Composition Tables of CESNID (Ribas-Barba *et al.* 2007).

Variables

BMI (weight (kg)/height^2 (metres)) was used as an indicator of general excess in total body fat independent of height. WHO's standard cut-off points were used to define general overweight (BMI 25-<30 kg/m^2) and obesity (BMI $\geq$30 kg/m^2) (WHO 1998). Underweight (BMI<18.5 kg/m^2) individuals (0.2% of men and 1.9% of women in 1992-1993 and 0.4% of men and 2.3% of women in 2002-2003) were combined with normal weight (BMI 18.5-<25 kg/m^2) individuals, since separating these two groups had no meaningful effect on results (not shown).

WC provided an index of abdominal fatness, which has more recently been included in efforts to classify obesity, as the distribution of body fat has been found to be important and carrying it around the abdomen has been found to be especially unhealthy (ICO 2010). The recommended sex-specific cut-off points for risk of metabolic complications were used: WC >94 cm (men) and WC >80 cm (women) for increased-risk (hereafter “IR WC”), and 102 cm (men) and 88 cm (women) for substantially-increased-risk (hereafter “SIR WC”) (WHO 2008).

Multivariate-adjusted associations between smoking history are reported for overweight and obesity combined (hereafter "overweight/obesity", as findings were generally similar for overweight and obesity when examined separately using multinomial logistic models, and the sample size for exploring obesity separately was limited given that very few smokers were obese (data not shown). Similarly, IR and SIR WC were combined in the multivariate models (hereafter IR/SIR WC), as findings were similar when these variables were examined separately (not shown).

Information on tobacco smoking was collected by self-report. Smoking history was defined as "never smoker", "former smoker" (had quit at the time of the interview but had smoked in the past for at least 6 months or longer) and “current smoker” (includes both daily and occasional smokers consuming <1 cigarette/day). Smoking intensity was defined as "light" (1-10 cig/d), "moderate" (11-20 cig/d) and "heavy" (>20 cig/d). Individuals smoking >20 cigarettes/day were considered as heavy smokers because this corresponds to the quantity of cigarettes contained in a standard pack in Western countries and other studies have also used this cut-off (Okuyemi *et al.* 2001; Rutten *et al.* 2009).

The covariates considered were: *sex*; *age*, defined as "20-40 years" and "41-60 years" (i.e. using the median age); *physical activity (PA) at work* –which was provided by questions adapted from the WHO physical activity “Countrywide Integrated Non-communicable Diseases Intervention” questionnaire (CINDI 1991) used in the ENCAT 1992–93 and ENCAT 2002–03 surveys- was defined as "sedentary", "light and moderate activity" and "active and very active" based on each subject's current employment, where sedentary occupations included those where most time is seated, light and moderate included standing occupations, and active or very active included manual occupations; *occupation social class* –for which the definition of Garcia-Alvarez *et al*. (2007) was used, although slightly modified- was defined based on the subject's occupation as: "low" (including farm labourer and fishermen, manual unskilled and skilled workers, craftsmen/skilled industry workers, amenities and machinery guards), "medium" (including foremen, rest of administrative staff, commercial and technical staff, service sector, army, medium-level technicians, business owners without employees, agriculture skilled professional, support technician, administrative staff, writers and artists), "high" (including high-level technicians, self-employed professionals – dentists, lawyers etc, business owners with employees, directors/managers), and "other" (including the unemployed, housewives and the non-classifiable); *education level of the subject and of the family´s head member* (ELS and ELH) as defined in García-Álvarez et al.; *ethanol consumption*, classified as "level 1" (0-9.99 g/day – men and women), "level 2" (men: 10.00-29.99 g/day, women: 10.00-19.99 g/day), "level 3" (men: ≥30.00 g/day, women: ≥20.00 g/day) (1 standard unit of alcoholic beverage in Spain is equivalent to 10 g of ethanol (Ministerio de Sanidad y Consumo 2007); *energy intake*, defined as "tertiles of intake (kcal/day)", *fruit and vegetable consumption*, defined according to recommendations (Aranceta, 2004; SENC 2001; WHO 2003) as "low" (<170g/day), "moderate" (170-400g/day)", "high" (>400g/day). Energy intake and fruit and vegetable consumption were obtained from the 24-hour recalls.

Statistical analysis

All analyses were performed with Intercooled Stata 8.0 for Windows (STATA Corporation, 98/95/NT. Texas, USA; 2002). In descriptive analyses, percentages were used to describe the prevalence of overweight, obesity, IR WC and SIR WC among men and women overall, and across smoking history strata; percentages were also used to describe the prevalence of smoking history by gender and age group. Weighted means with standard errors (SE) and proportions were used to describe the distribution of other variables across smoking history groups.

Multivariate-adjusted associations between smoking history variables and each obesity outcome (both for BMI and WC) were estimated using simple logistic regression. Separate models were fit for each survey, and for men and women; age-adjusted and multivariate adjusted results are presented. Models analyzed odds of "overweight/obesity", and "IR/SIR WC" among stratified current (light:<10/day), moderate:11-20/day) and heavy:>20/day) and former smokers vs. never smokers (the referent group). No data on smoking intensity was available for former smokers.

Variables included as confounders in the final multivariate models were: age, education level, occupation level, PA level at work, alcohol (ethanol) consumption, energy intake and fruit and vegetable consumption. Confounder selected included all variables that changed odds ratios (OR) of interest by >10% in at least some models. Within the analysis sample, sensitivity analyses were also carried out to assess whether missing values for covariates were influential, confirming that excluding subjects with missing values did not influence the main associations of interest (not shown). Final models excluded subjects with missing values for all covariates included. Results are presented as odds ratios and 95% confidence intervals (CIs). Mantel-Haenzel test for trend was used to determine whether there was a dose-dependent relationship between smoking history/intensity and BMI and between smoking history/intensity and WC ($p<0.05$ as significance level). All prevalence estimates and ORs were weighted using the Catalan census population of 1991 and 2001 (IDESCAT: Estructura de la població, 1975–2003) respectively, accounting for the population gender and age group distribution.

2.2.3 Results

Prevalence and trends in general and central obesity

Levels of overweight/obesity were substantial, and consistently higher in men than in women (55.3% vs. 44.4% in 1993 and 64.7% vs. 42.2% in 2003, $p<0.05$); levels of IR/SIR WC, also substantial, were initially higher in women than in men (35.9% in men vs. 48.6% in women p<0.05) but very similar in the second survey (men 50.9% vs. women 49.1%, $p<0.05$) (Table 13).

Over time, there was a substantial increase in the prevalence of obesity (7%) as well as in SIR WC (11%) in men, though levels of overweight and IR WC were fairly stable. Among women, there was a substantial increase in the prevalence of SIR WC (7%), though overweight and obesity levels remained fairly stable and IR WC declined. Thus overall, among men, there were increases in overweight/obesity (55.3% and 64.7% in 1992-1993 and 2002-2003 respectively) and IR/SIR WC (35.9% and 50.9%), while among women levels of overweight/obesity (44.5% and 42.2%) and IR/SIR WC (48.6% and 49.1%) remained fairly stable, albeit with an increase in the prevalence of SIR WC (Table 13).

Table 13. Prevalence of overweight[a], obesity[b], IR WC[c] and SIR WC[d], by gender and survey.

	Men		Women	
	ENCAT 1992-93 (n=502)	**ENCAT 2002-03 (n=595)**	**ENCAT 1992-93 (n=602)**	**ENCAT 2002-03 (n=590)**
Overweight/obesity[e]	55.3%	64.7%	44.4%	42.2%
Overweight	46.8%	49.2%	31.0%	28.4%
Obesity	8.5%	15.5%	13.5%	13.8%
IR/SIR WC[f]	35.9%	50.9%	48.6%	49.1%
IR WC	24.0%	28.1%	24.8%	18.4%
SIR WC	11.9%	22.8%	23.8%	30.7%

a.Overweight= BMI 25-<30 kg/m^2; b. Obesity= BMI ≥30 kg/m^2; c.IR WC= Increased-risk of metabolic complications (i.e. WC >94 cm for men and WC >80 cm for women); d. SIR WC= Substantially-increased-risk of metabolic complications (i.e. WC >102 cm for men and WC >88 cm for women); e. Overweight/obesity = overweight plus obese subjects; f. IR/SIRWC = subjects with IR WC plus subjects with SIR WC.

Prevalence and characteristics of never, former and current smokers

In 1992-1993, 53.6% of men and 30.8% of women reported being current smokers. Over time, as shown in Table 14, the prevalence of current smoking decreased substantially in men (by 13%), though only slightly in women (2%), while the percent of former smokers increased (by almost 4% in men and by 9% in women). The prevalence of heavy smoking (>20/day) declined from 10.9% to 8.2% in men, and from 3.2% to 2.1% in women (not shown). Table 14 also shows that, among males, both mean BMI and WC increased in all smoking history groups, with larger increases among never than former or current smokers (4.8 cm vs. 3.0 cm for WC). Among female never smokers, however, mean BMI and WC decreased over time, while both measures of obesity increased among former and current smokers. Moreover, among men in both surveys, current smokers had the highest percentages of low occupational social class, low levels of education, sedentary physical activity at work, low fruit and vegetable consumption and high ethanol consumption. However, among females, these percentages were highest in never smokers.

Table 14. Male and female characteristics by survey and cigarette smoking history.*

Characteristics	Cigarette smoking history					
	Never		Former		Current	
ENCAT	**1992-93**	**2002-03**	**1992-93**	**2002-03**	**1992-93**	**2002-03**
MEN	26.1%	35.9%	20.3%	23.9%	53.6 %	40.2%
Age (years)	40.6 (0.98)	40.1 (0.75)	44.9 (1.08)	45.3 (0.84)	40.0 (0.69)	38.7 (0.66)
BMI (kg/m^2)	25.6 (0.28)	26.6 (0.29)	26.5 (0.33)	26.9 (0.29)	25.2 (0.21)	26.1 (0.26)
WC (cm)	89.5 (0.82)	94.3 (0.85)	92.5 (1.05)	95.5 (0.91)	89.8 (0.65)	92.8 (0.77)
Percent low social class**	25.8%	35.4%	22.2%	25.3%	52.0%	39.4%
Percent low education level‡ (< 6 years)	24.4%	29.5%	31.3%	24.8%	44.3%	45.7%
Percent low HH education level¥ (< 6 years)	27.8%	35.8%	25.1%	21.1%	45.2%	43.2%
Percent sedentary occupational physical activity	33.0%	37.8%	23.3%	25.5%	43.8%	36.7%
Total energy intake (kcal/d)	2209.2 (38.8)	2173.2 (26.8)	2121.2 (48.7)	2112.2 (32.6)	2219.9 (33.9)	2139.5 (29.6)
Percent low fruit & vegetable consumption (<170g/d)	21.8%	31.9%	11.2%	16.4%	67.1%	51.7%
Percent high ethanol consumption (level 3)	29.9%	14.3%	5.0%	42.4%	65.1%	43.3%
WOMEN	56.9%	49.5%	12.3%	21.3%	30.8%	28.8%
Age (years)	45.1 (0.63)	42.8 (0.63)	36.5 (0.86)	41.4 (0.81)	35.2 (0.70)	38.0 (0.71)
BMI (kg/m^2)	26.6 (0.31)	25.2 (0.25)	23.6 (0.42)	25.1 (0.43)	23.5 (0.27)	24.5 (0.35)
WC (cm)	83.5 (0.78)	82.4 (0.71)	76.5 (1.19)	82.1 (1.12)	76.8 (0.70)	80.6 (1.01)
Percent low social class**	68.1%	54.3%	6.3%	19.7%	25.6%	25.9%
Percent low education level‡ (< 6 years)	76.5%	64.9%	6.9%	14.3%	16.6%	20.8%
Percent low HH education level¥ (< 6 years)	65.8%	60.6%	5.1%	15.7%	29.1%	23.7%
Percent sedentary occupational physical activity	48.4%	46.6%	13.9%	20.9%	37.7%	32.5%
Total energy intake (kcal/d)	1606.7 (20.4)	1661.5 (19.2)	1627.8 (33.2)	1671.7 (30.0)	1684.9 (23.5)	1663.9 (25.9)
Percent low fruit & vegetable consumption (<170g/d)	45.9%	40.5%	10.9%	16.0%	43.3%	43.5%
Percent high ethanol consumption (level 3)	52.3%	47.1%	18.8%	9.4%	29.0%	43.5%

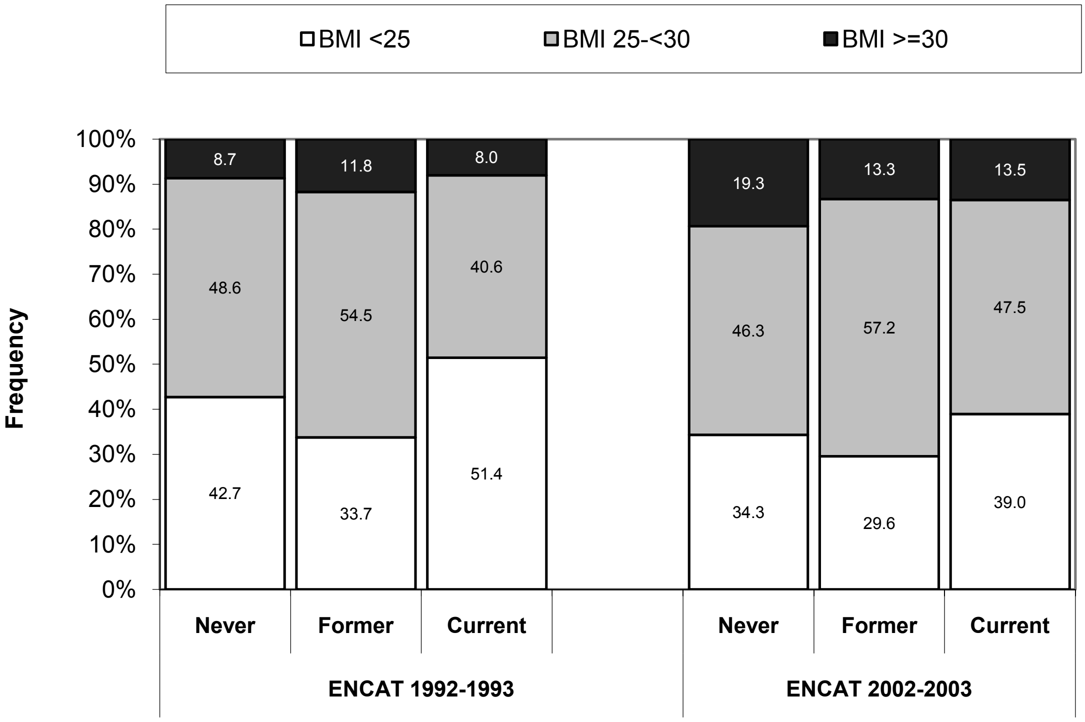
* Values are proportions or means (SE) as shown.
**Low occupational social class defined based on the household head's occupation being manual or unskilled workers, as well as farmers or fishermen.
‡Low education level defined as< 6 years of schooling for each individual.
¥Low household head (HH) education level defined as< 6 years of schooling.

Shifts in the prevalence of general and central obesity by smoking history group

Figures 21 and 22 show prevalence rates of general and central obesity by smoking history. In 1992-1993, among men, former smokers had the highest prevalence of overweight, obesity, and both IR and SIR WC. By 2002-2003, however, substantial increases among never and current smokers led to levels of general and central obesity similar to those in former smokers. More specifically, in 2002-2003, while former smokers had the highest prevalence of overweight (57.2%) and SIR WC (28.2%), never smokers had the highest rates of obesity (19.3%) and current smokers had the highest level of IR WC (30.7%).

In contrast to men, among women, in 1992-1993 the prevalence of overweight, obesity, IR WC and SIR WC was highest among never smokers. As among men, however, in 2002-2003 disparities in prevalence rates across smoking groups were substantially diminished as a consequence of increased levels in both former and current smokers, as well as lower levels in never smokers.

Figure 21. Prevalence of BMI categories in male (top) and female (bottom) never smokers, former smokers and current smokers, by Survey. ENCAT 1992-1993 and 2002-2003.



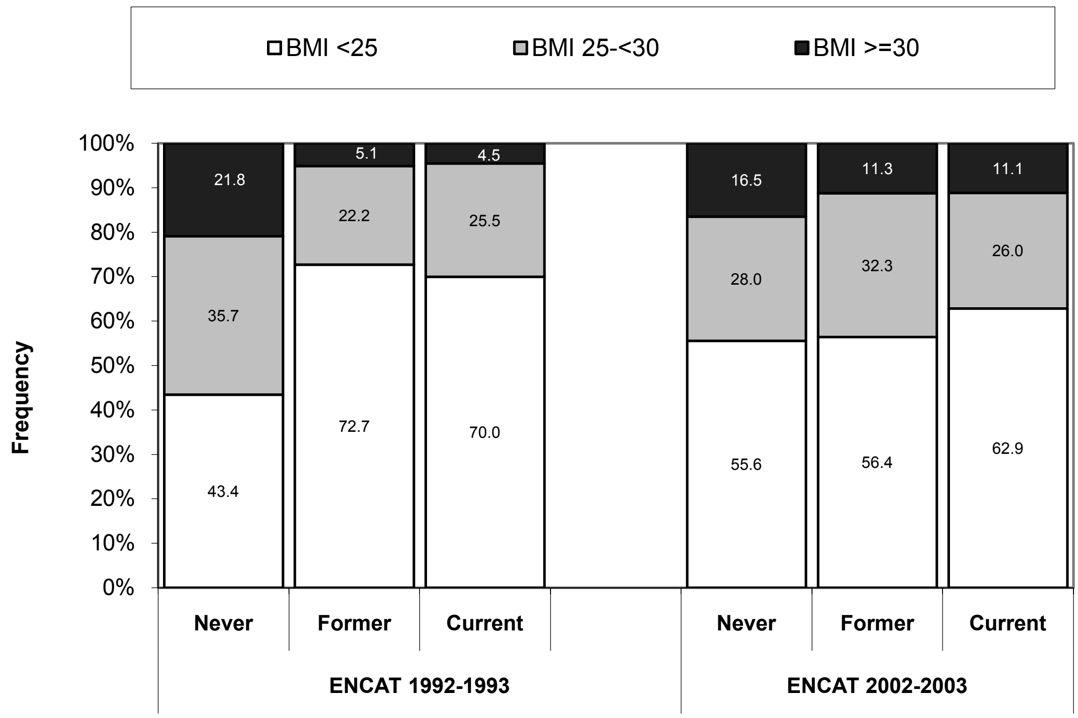
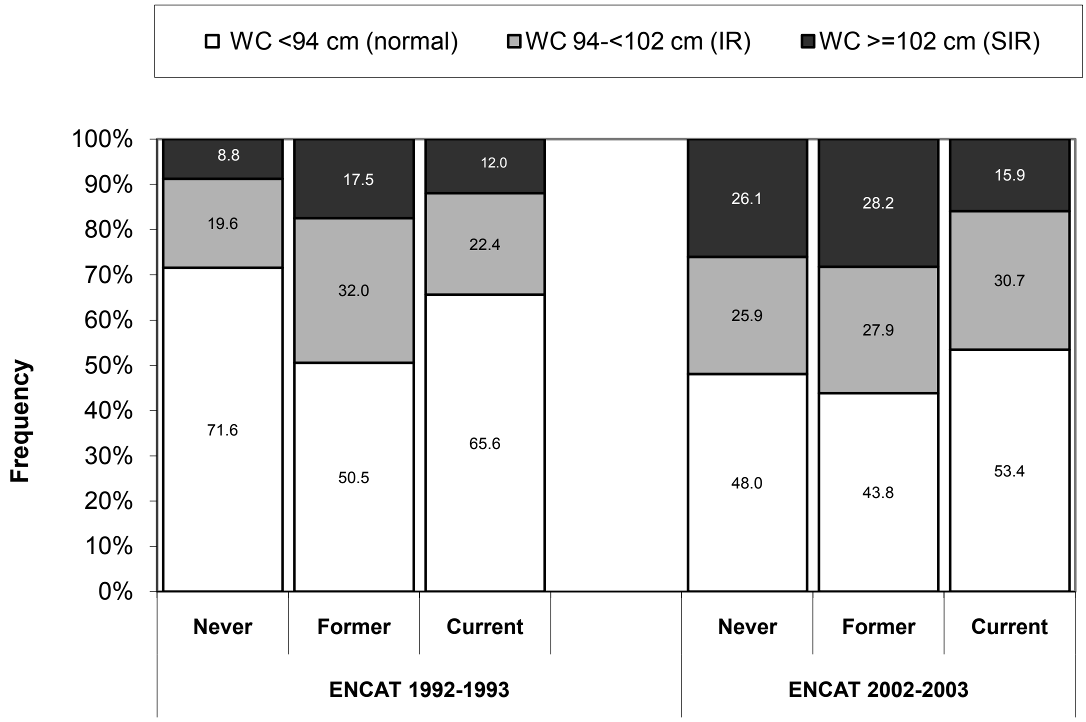
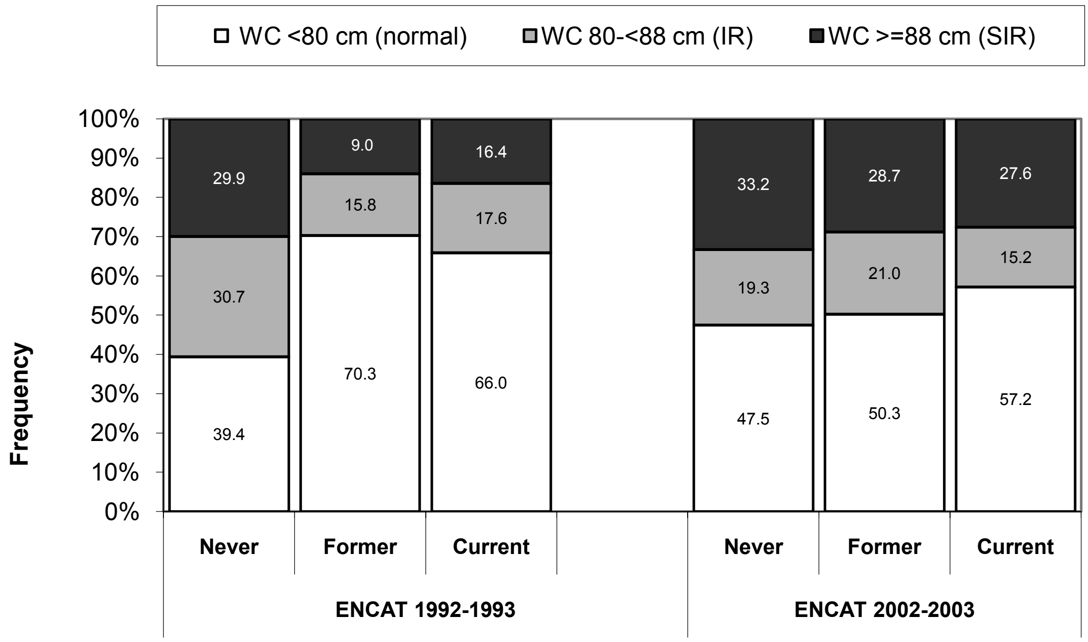


Figure 22. Prevalence of WC categories in male (top) and female (bottom) never smokers, former smokers and current smokers, by Survey. ENCAT 1992-1993 and 2002-2003.





Associations between smoking history and general and central obesity: 1992-1993

Age- and multivariate-adjusted associations between smoking history and overweight/obesity and IR/SIR WC are presented in Table 15. In 1992-1993, the multivariate-adjusted analysis showed that male moderate and heavy smokers were 0.40 and 0.63 times less likely to be overweight/obese than never smokers, although the association was only significant ($p<0.05$) for moderate smokers. Neither former smoking nor current-light smoking was associated with general obesity among men. For central fatness, however, both male former and current-heavy smoking were associated with a more than two-fold increased odds of IR/SIR WC compared to never smoking ($p<0.05$).

In contrast to the null association among men, women who were current-light smokers were significantly less likely to be overweight/obese than never smokers (OR 0.42, CI 0.22-0.81). For central fatness, both former and current-light smokers had lesser odds of an IR/SIR WC than never smokers, with associations significant at the 10 and 5% level respectively, again contrary to the positive association between central fatness and former smoking observed in men.

Results of the Mantel-Haenszel test for trend (Table 15) show a significant trend ($p=0.007$) only in male BMI overweight/obesity-smoking OR; in females however, OR for both BMI overweight/obesity-smoking and IR/SIR WC-smoking show a significant trend ($p=0.000$ and $p=0.006$ respectively).

Associations between smoking history and general and central obesity: 2002-2003

In 2002-2003, when the prevalence rates of general and central obesity were notably higher, particularly in men, a rather different situation emerged, with most associations strongly attenuated compared to those observed in 1992-1993. Thus among men, current moderate and heavy smoking were no longer associated with general overweight/obesity, and former smoking was no longer associated with IR/SIR WC. However, current heavy smoking remained associated with IR/SIR WC, although the magnitude of the association was nearly two-fold rather than three-fold.

Associations were similarly attenuated towards the null among women in 2002-2003. Current light smoking was no longer associated with reduced odds of overweight/obesity or with reduced odds of IR/SIR WC, and former smoking was no longer associated with reduced odds of IR/SIR WC. However, current moderate smokers were 0.57 times less likely to have an IR/SIR WC as compared to never smokers, although the association was very weak ($p<0.10$).

Results of the Mantel-Haenszel test (Table 15) show a significant trend in female BMI overweight/obesity-smoking OR and IR/SIR WC-smoking OR ($P=0.046$ and $P=0.025$ respectively), but not in any of the male OR.

Table 15. Associations between smoking history and overweight/obesity and increased-risk/substantially-increased-risk WC (IR/SIR WC).

Smoking history	Overweight/obesity (BMI ≥25 kg/m^2)				IR/SIR WC (WC>94 cm in men, WC>80 cm in women)			
	ENCAT 1992-93		ENCAT 2002-03		ENCAT 1992-93		ENCAT 2002-03	
	n	OR (95% CI)	n	OR (95% CI)	n	OR (95% CI)	n	OR (95% CI)
AGE-ADJUSTED ASSOCIATIONS								
Men	469		508		468		507	
Never (ref)	74	1.0	121	1.0	37	1.0	95	1.0
Former	68	1.23 (0.67-2.25)	88	0.98 (0.58-1.65)	50	**2.03*(1.08-3.81)**	70	0.94 (0.57-1.56)
Current light (<=10cig/day)	48	1.23 (0.65-2.31)	40	0.72 (0.39-1.32)	22	0.94 (0.47-1.89)	29	0.67 (0.36-1.24)
Current moderate (11-20cig/day)	46	**0.47*(0.26-0.83)**	46	0.81 (0.45-1.46)	34	1.13 (0.60-2.10)	31	0.67 (0.38-1.17)
Current heavy (>20cig/day)	24	0.61 (0.30-1.21)	31	1.22 (0.56-2.66)	24	**2.51*(1.22-5.14)**	29	**1.82‡(0.87-3.83)**
Women	579		611		574		610	
Never (ref)	187	1.0	151	1.0	195	1.0	174	1.0
Former	20	**0.51*(0.27-0.98)**	58	1.02 (0.65-1.61)	22	**0.48*(0.25-0.91)**	66	0.94 (0.59-1.48)
Current light (<=10cig/day)	24	**0.48*(0.26-0.89)**	34	1.01 (0.60-1.69)	23	**0.42*(0.22-0.78)**	41	0.95 (0.57-1.56)
Current moderate (11-20cig/day)	24	0.85 (0.42-1.75)	21	0.65 (0.35-1.22)	30	1.06 (0.54-2.12)	23	**0.53*(0.29-0.97)**
Current heavy (>20cig/day)	8	1.09 (0.40-2.99)	6	**1.13*(2.18-4.33)**	6	0.84 (0.29-2.46)	7	1.09 (0.26-4.60)
MULTIVARIATE-ADJUSTED ASSOCIATIONS								
Men	443		503		442		502	
Never (ref)		1.0		1.0		1.0		1.0
Former		1.33 (0.69-2.54)^a		0.97 (0.57-1.67)^c		**2.37*(1.19-4.69)**^{b}		1.01 (0.61-1.68)^d
Current light (<=10cig/day)		1.00 (0.52-1.93)^a		0.73 (0.39-1.36)^c		0.93 (0.46-1.92)^b		0.71 (0.37-1.35)^d
Current moderate (11-20cig/day)		**0.40*(0.22-0.75)**^{a}		0.75 (0.41-1.36)^c		1.12 (0.59-2.22)^b		0.58 (0.32-1.04)^d
Current heavy (>20cig/day)		0.63 (0.31-1.29)^a		1.11 (0.50-2.51)^c		**2.73*(1.21-6.16)**^{b}		**1.98‡(0.91-4.31)**^{d}
MH# test for trend		0.007		0.481		0.904		0.986
Women	528		591		523		590	
Never (ref)		1.0		1.0		1.0		1.0
Former		0.71 (0.37-1.38)^a		1.27 (0.78-2.05)^c		**0.56‡(0.29-1.09)**^{b}		1.14 (0.71-1.83)^d
Current light (<=10cig/day)		**0.42*(0.22-0.81)**^{a}		1.20 (0.67-2.13)^c		**0.39*(0.20-0.77)**^{b}		1.15 (0.68-1.93)^d
Current moderate (11-20cig/day)		0.76 (0.36-1.60)^a		0.71 (0.37-1.36)^c		1.00 (0.49-2.05)^b		**0.57‡(0.30-1.09)**^{d}

OR= odds ratio, CI = confidence interval. BMI= body mass index; overweight= BMI 25-<30 kg/m^2; obesity= BMI≥30 kg/m^2; overweight/obesity = overweight plus obese subjects. WC= waist circumference; IR WC/SIR WC = subjects with IR WC plus subjects with SIR WC; IR WC= Increased-risk of metabolic complications (i.e. WC>94 cm for men, WC>80 cm for women); SIR WC= Substantially-increased-risk (i.e. WC>102 cm for men, WC>88 cm for women); *p<0.05; ‡p<0.10. #MH=Mantel-Haenszel. a. Adjusted for age, energy intake, physical activity level at work, ELS and SES-occupation. b. Adjusted for age, energy intake, ELS and fruit and vegetable consumption. c. Adjusted for age, energy intake, ELH, ELS, SES-occupation, fruit and vegetable consumption and ethanol consumption. d. Adjusted for age, energy intake, ELS, SES-occupation and ethanol consumption.

2.2.4 Discussion

The analysis of these two samples of adults from the region of Catalonia yielded very different results and may illustrate the trends in tobacco use and its body weight implications in a Mediterranean setting.

The 1992-93 general overweight, obesity and excess central fatness prevalence rates were higher in male former smokers and female never smokers. Similar results showing lower BMI in current smokers have been reported by other studies (Lissner *et al.* 1992; Molarius *et al*. 1997; Martínez *et al.* 1999; Canoy *et al*. 2005; Akbartabartoori *et al.* 2005; Pisinger & Jorgensen 2007; Travier *et al*. 2009). However, findings by John et al. (2005) only agree with our female results, as they found lower overweight or obesity in female heavy smokers as compared to never smokers; nevertheless, our results from heavy smoking in women could not be properly analyzed because the sample size was too small. For males, they found higher proportions of overweight or obesity among moderate smokers as compared to never smokers.

Between 1992-93 and 2002-03, current smoking prevalence, initially more than 50%, declined substantially in men, though it remained fairly stable among women (30.8-28.8%). Other authors that studied the period 1982-1998 also found decreasing smoking prevalence trends among Catalan men, but increasing trends among Catalan women and young adults of both sexes, concluding that tobacco smoking rates were stable (Jané *et al* 2001). Using data from 2005, the WHO reported similar percentages of tobacco use among Spanish adults, which ranged between 28.6-36.5% (WHO 2008).

In addition, levels of overweight, obesity and IR/SIR WC were substantial in 1992-93, but there were nonetheless substantial increases over time, particularly in obesity and SIR WC. According to the ENRICA study (Banegas *et al.* 2010), in Catalonia, by 2010, male general obesity prevalence had reached a 23.7% (an 8-point increase if compared to ENCAT 2003) and that of female a 21.2% (a 7-point increase when compared to ENCAT 2003). The increases in obesity and SIR WC observed in ENCAT were highest among male never smokers, but were also substantial among current female smokers, with smaller increases in former smokers.

Moreover, associations between current smoking intensity and general obesity, adjusted for confounders such as subject's age, energy intake, physical activity at work, education level and occupation, were initially strongly negative in men for moderate and heavy smoking, and in women for light smoking. By 2002, null associations were observed, indicating that current smokers were no longer leaner than never smokers.

With some exceptions indicating no association (Clair *et al* 2011), the majority of studies on this topic have found negative associations between current smoking—especially moderate and heavy smoking—and general obesity (Canoy *et al.* 2005; Xu *et al.* 2007; Bamia *et al*. 2004; Travier *et al.* 2009; John *et al.* 2005). No previous studies have looked at changes in associations coinciding with shifts in the prevalence of obesity and smoking over time. These shifts in results suggest that the increased overweight and obesity among current smokers diminish disparities in prevalence vs. never smokers.

Mechanisms for a possible causal relationship between current smoking and a lower BMI may include the increased metabolic rate induced by nicotine (Clair *et al.* 2011; Hofstetter *et al.* 1985; Chiolero *et al*. 2008), the decreased metabolic efficiency or the decreased caloric absorption (reduction of appetite) (Chiolero *et al*. 2008; Lloveras *et al.* 2001; Mineur 2011) or the lower consumption of desserts that some authors have observed in men (but higher in women) (Lloveras *et al.* 2001); an increased total energy expenditure involving the stimulation of the sympathetic nervous system (Hofstetter *et al.* 1985), although weaker among obese subjects (Audrain *et al.* 1995) and also depending on physical activity and fitness degree (Perkins *et al*. 1994; Perkins & Sexton 1995).

In contrast, despite negative associations with general overweight/obesity, there were strong positive associations between current heavy smoking—but not moderate or light smoking—and central obesity in men. These associations were only slightly attenuated in 2002: this was the most persistent association observed. Among women, moderate and the small number of heavy smokers had similar levels of IR/SIR WC as did never smokers, although current light smoking was initially associated with reduced odds of IR/SIR WC; by 2002, however, after multivariate adjustment, female light smokers had similar levels of IR/SIR WC to those of never smokers, and moderate smokers, unexpectedly, had lower levels ($p<0.10$).

Our finding of a positive association for heavy smoking in men is again in line with results reported by Travier *et al.* (2009) and Clair *et al.* (2011), who found heavy smoking to be positively associated with elevated WC, though in those studies this was observed in both sexes. Clair *et al.* (2011) however, did observe a positive association between moderate smoking and elevated WC in men. On the other hand, the negative association between moderate smoking and central obesity in women is in line with Travier et al.'s findings, which observed a lower elevated WC in female current smokers of the average number of cigarettes, but did not observe this in men. Again, changes in associations at different points in time have not been reported previously, but results in men suggest that disparities between current smokers and never smokers are diminished as levels of central obesity rise among the never smokers.

A possible mechanism for a greater WC among smokers is, for instance, the higher fasting plasma cortisol concentrations seen in smokers as compared to non-smokers, which are strongly associated with visceral adipose tissue (VAT) (Cryer *et al.* 1976; Friedman *et al.* 1987), in turn strongly associated with WC (Han *et al.* 2006); higher cortisol concentrations could be a consequence of the stimulation of sympathetic nervous system activity that is induced by smoking (Williamson *et al.* 1991; Yoshida *et al.* 1999). In addition, sex hormones may be involved. In women, low concentrations of estrogens and an excess of androgens such as testosterone - typically seen after menopause (Haarbo *et al.* 1991) - has been associated with VAT accumulation (Haarbo *et al.* 1991; Bjorntorp 1988; Evans *et al.* 1988). In men, VAT increases when testosterone concentrations decreases (Vermeulen *et al.* 1999), and testosterone administration in middle-aged men reduces VAT by increasing lipolysis (Marin 1995). Smoking may reduce testosterone concentrations (Vermeulen *et al.* 1999; Marin 1995; Meikle *et al.* 1988). However, in the case of heavy smokers, the mentioned increase in metabolism induced by nicotine might be outweighed by the metabolic effects of nicotine that favour abdominal fat accumulation and the smokers propensity for unhealthy lifestyle habits, thus causing an inverse relationship for heavy smokers and WC as compared to light smokers (Clair *et al.* 2011; Chiolero *et al.* 2008).

In 1992-93, age-adjusted associations between former smoking and general overweight/obesity were weakly positive in men but strongly negative in women as compared to never smokers; after multivariate adjustment for confounders such as subject's age, energy intake, physical activity at work, education level and occupation, both the positive and negative associations seen in men and women respectively were attenuated. However, it is important to note that associations with former smoking were strongly diminished over time, as the prevalence of obesity increased more among never and current smokers. Our results are in line with those by John *et al*. (2005), who found that former smokers did not reveal more overweight or obesity than never smokers, suggesting that a short-term increase in body weight after smoking cessation does not become critical in public health terms when never smokers are taken as the reference group. Other authors, however, have reported different results for male former smokers indicating that they weigh more than never smokers (Travier *et al.* 2009; Molarius *et al.* 1997; Pisinger & Jorgensen 2007). Mechanisms for weight gain among male former smokers might include higher energy intake, decreased resting metabolic rate and physical activity and possibly changes in adipose tissue metabolism (Ferrara *et al.* 2001; Filosof *et al*. 2004). Moreover, it has been suggested that more female than male quitters might develop decisions or psychological strategies that are strong enough to curb weight gain (John *et al.* 2005; Davis *et al.* 2004).

Associations between former smoking and central obesity: in 1992-93 were strongly positive in men as compared to never smokers, persisting even more strongly positive after multivariate adjustment for age, energy intake, subject's education level and fruit and vegetable consumption; these results have been found previously in men (Xu *et al*. 2007). In women, however, age-adjusted associations were strongly negative, persisting at a lower significance level (10%) after multivariate adjustment. These results for both men and women are in line with those of Travier *et al.*'s (2009), although they analysed the association in former smokers of the average time since quitting. In contrast, Pisinger and Jorgensen (2007) observed that female quitters had a higher increase in WC than men. Nevertheless, our results show that by 2002-03, when levels of central obesity had increased especially in the never and current smokers, no association between former smoking and central obesity was observed.

Moreover, it is important that results have been derived from multivariate-adjusted analyses with the intention to eliminate as much as possible the effect of confounders such as physical activity, energy intake or alcohol consumption on the relationship between smoking and general/central fatness. In this sense, Chiolero *et al.* (2008) suggested that, heavy smokers tend to have greater body weight than light smokers or non-smokers because heavy smokers are more likely to adopt behaviours favouring weight gain (e.g. low physical activity, unhealthy diet, and high alcohol intake) than are light smokers or non-smokers. It is noteworthy that we found very little disparity in age-adjusted vs. multivariate-adjusted results, and the list of variables included in the adjustment did not explain persistent positive associations between current heavy smoking and central obesity (in men).

The reasons for the observed gender disparities are unclear. Previous studies reporting gender disparities are also found in the literature (Barret-Connor & Khaw 1989; Akbartabartoori *et al.* 2005; Canoy *et al.* 2005; Travier *et al.* 2009; Clair *et al.* 2011). However, other studies that have considered the effects of confounding factors such as alcohol and food intake, physical activity, and education still showed similar findings between sexes (Troisi *et al*. 1991; Visser *et al.* 1999; Bamia *et al.* 2004). It has been argued that the sex difference could be explained by a stronger antiestrogenic effect of nicotine in women as compared to men (Tanko & Christiansen 2004). Heterogeneity in the results could be caused by differences in sample sizes, because smaller studies are less likely to detect modest effects, variation in reporting smoking variables and other important confounders, and age structure of the population (Canoy *et al.* 2005). In our study, the very small number of women who reported themselves to be heavy smokers may be limiting the ability to examine associations between current heavy smoking and central obesity and compare them with those observed in men.

We recognise the following study limitations: the cross-sectional nature of the surveys, which does not allow us to establish any definitive temporal association between smoking and general/central adiposity; relying on self-reported measures of smoking habits; using surrogate markers for fat distribution; the missing data on anthropometry (outcomes) and smoking history (exposure) variables, although, no significant differences in terms of age, education and socio-economic status (occupation) were observed when the sample of individuals with missing data on outcome and exposure variables was compared with the sample that had all data.

Regarding confounders, some important factors observed in other studies to have had a large/meaningful impact on the smoking-general/central fatness relationship and, which were available for our analyses, include age, energy intake, physical activity/exercise, alcohol consumption, education level (John *et al.* 2005; Travier *et al.* 2009; Xu *et al.* 2007) and socioeconomic status (Xu *et al.* 2007; Wild & Byrne 2006; Healton *et al.* 2006), although they had a minimal impact on our results and in other studies (Clair *et al.* 2011). Failing to adjust for potential confounders described in other studies such as residence (Xu *et al.* 2007), weight cycling (Lissner *et al.* 1991), location of work/urbanization (Flegal *et al.* 1995; Chen *et al.* 1993), menopausal status (WHO 2008; Travier *et al.* 2009), parity – associated with increases in WC (WHO 2008), marital status (Flegal *et al*. 1995), snacking, sugary drinks consumption, hours seated, total fibre, fast food and BMI (Basterra-Gortari *et al.* 2010) is unlikely to have had a large impact; but we cannot totally rule out the effect of confounding caused by factors that we have not considered.

The major strengths of the present study include: that it uses measured anthropometry; that it is based on two general population samples of relatively large total size, which provide a rather good number of explanatory factors (potential confounders) and detailed information on current smoking intensity; but most importantly, it is based on two methodologically very similar samples that are 10-years apart, which allows for comparison and trends identification.

We conclude that although causality cannot be established, results suggest a positive association between heavy smoking and central fatness among men, but no association between former smoking and general/central fatness; findings strengthen arguments for promoting smoking cessation to reduce morbidity and mortality associated with both smoking and obesity.

2.3 - Chapter 3:

Usage of plant food supplements across six European countries: findings from the PlantLIBRA PFS Consumer Survey 2011-2012

2.3.1 Introduction

Botanicals and their derivatives/preparations are used throughout Europe for health purposes, with increased usage in the general population as well as among specific subgroups encompassing children and pregnant women or those suffering from diseases such as cancer among others (Menniti-Ippolito *et al.* 2002; Ritchie 2007; Adams *et al.* 2009; Bishop & Lewith 2010). Botanicals are used in many different types of products, including foods, (teas and juices), food supplements such as plant food supplements (PFS), herbal medicinal products (HMP), homeopathic products, cosmetics, biocides etc (Larrañaga-Guetaria 2012). These different product categories are regulated by specific legislation, depending on the intended use of the product.

The European Union (EU) Directive on Food Supplements (2002/46/EC) defines dietary supplements (which include PFS) as (European Parliament & Council 2002):
"…foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles and other similar forms of liquids and powders designed to be taken in measured small quantities".

The marketing of a product as a PFS however, depends on national legislation, which differs widely across Member States. Countries vary in the extent to which products are regulated, as well as in the process of regulatory control. Some countries have regulated the use of botanicals in detail (including negative and positive lists), some apply specific conditions of use, (including maximum usage levels or warnings for the consumer), and in others less specific requirements exist. An added complexity lies in the application of the basic European "principle of mutual recognition", whereby any product that is lawfully marketed in one Member State can be sold in all 27 Member States (Larrañaga-Guetaria 2012).

Moreover, the same botanical may be used as a food supplement and as a medicinal product, depending on the intended use of the product and both food supplements and medicinal products often share the same form of presentation (powders, pills or tablets). Hence the legal status of products differs from one country to another, resulting in a complex market environment. This so-called borderline issue between PFS and HMP is a major obstacle to the marketing of PFS in the EU (Larrañaga-

Guetaria 2012).

Plant food supplement usage data at EU level are scarce with reports providing PFS market data as opposed to data reported directly by the consumer (EAS 2007). Surveys on the intake of botanicals have been conducted primarily in the context of the intake of dietary supplements in general (Skeie *et al*. 2009) or as part of surveys of complementary and alternative medicine (CAM) therapies (Vargas-Murga *et al.* 2011), and issues such as the legal distinction between HMP and PFS have not been taken into account. A recent systematic review evaluating the demographic characteristics and health status factors associated with CAM use reported that the majority of population based consumption studies had been conducted in the USA (64% of the 110 identified studies), and of these, 13% were in Europe, with the majority carried out in Scandinavia (7%) and the United Kingdom (5%) (Bishop & Lewith 2010). Studies have been limited by the heterogeneity of definitions used, study designs and objectives making it difficult to compare results and to extrapolate conclusions. The ambiguity of categories such as ‘‘natural medicine’’, ‘‘herbal remedies’’ or ‘‘herbal medicine’’ and what constitutes ‘‘dietary supplements’’ makes it nearly impossible to attain reliable estimates of the prevalence of PFS usage in Europe, with only limited data available at national levels (Vargas-Murga *et al.* 2011; Harrison *et al.* 2004; INFITO 2007) But not at the European level.

A study by the European Advisory Services (EAS) on “The use of substances with nutritional or physiological effect other than vitamins and minerals in food supplements” (EAS 2007), provided information on European market and regulation data, and highlighted the need for obtaining PFS usage data in order to plan, monitor and evaluate national and European policies, as in other regions of the world. One such example is the United States of America, where the Alternative Health/CAM supplement of the National Health Interview Survey (NHIS) has been collecting data on botanical dietary supplements for some years now (NCHS 2003; Bardia *et al.* 2007; Dwyer *et al.* 2013).

The EFSA has recognised the lack of data in the sector and has published a number of reports addressing related issues, namely the recommendations for reporting the use of supplements and medicines by adults in any pan-European dietary survey or project (EFSA 2009), and the “Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health”, aimed to help with the safety assessment of botanicals and botanical preparations intended for use as food supplements (EFSA 2012).

The purpose of this paper is to describe the type and frequency of PFS usage reported in a retrospective survey of consumers in six European countries; in addition we present the most frequently used botanical ingredients in these products. We also highlight the issues associated with measuring usage of PFS in European populations and make recommendations for future research.

2.3.2 Materials and methods

Ethics statement

Before initiating the fieldwork, approval for the conduct of the survey was obtained from four ethics committees: the Bioethics Commission of the University of Barcelona, Spain; the Ethics Committee of the University of Milano, Italy; the Ethical Committee of the Faculty of Medicine - Transilvania University of Brasov, Romania; and the Coordinating Ethics Committee, Hospital District of Helsinki and Uusimaa, Finland. Approval of the survey by these four ethics committees required submitting all survey material to their members for evaluation. No ethical approval for the survey was needed in Germany and the United Kingdom.

To ensure harmonisation and standardisation of the fieldwork and data collection across countries, a market research organization, European Fieldwork Group (EFG) was subcontracted to implement the survey. The survey was conducted by EFG in strict accordance with the ICC/ESOMAR Code on Market and Social Research. In all countries, informed consent was obtained verbally from all respondents after reading the survey information sheet. All data were recorded manually i.e. pen-and-paper. Recruitment of survey participants occurred in the selected cities in each country. Approximately the first 1000 individuals per country were systematically selected for screening i.e. intercepting 1 in every 5 individuals passing by to ask him/her the initial screening questions; subsequent screening selection was performed on a convenience basis i.e. intercepting individuals in places where consumers were likely to be found, such as herbal shops, pharmacies etc. Eligible respondents who agreed to participate were given an appointment at their home/workplace to complete the main survey. The appointments of those willing to participate were later reconfirmed by phone.

The data were made anonymous when recorded electronically i.e. the respondents' contact details were not entered into the survey database. Instead, the market research organization assigned ID numbers to each respondent and provided PlantLIBRA partners only the database with the assigned ID numbers.

Definition of plant food supplements in the PlantLIBRA PFS consumer survey

Although there is a legal definition of Food Supplements (EU Directive (2002/46/EC) (European Parliament & Council 2002) under which PFS reside, for the purposes of this research it was necessary to develop a specific definition of PFS whose main characteristic is that they contain botanical preparations as ingredients for food supplementation.

Botanical preparations are obtained by subjecting botanicals (plants, algae, fungi or lichens) to treatments such as comminution, extraction, distillation, squeezing, fractionation, purification, concentration or fermentation. These include extracts, essential oils, expressed juices, powders, etc.

Botanical preparations can be considered as *nutrients* or *other substances*. Thus, the definition of PFS for the survey was as follows: PFS are "foodstuffs the purpose of which is to supplement the normal diet and which are *concentrated sources of botanical preparations* that have nutritional or physiological effect, alone or in combination with vitamins, minerals and other substances which are not plant-based. PFS are marketed in dose form, such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities".

Products that did not meet this definition, such as herbal remedies and other medicinal products based on botanicals, and those that did not meet the PFS definition in terms of dosage, such as herbal teas or juices, were excluded.

Sample population and PFS consumer definition

A cross-sectional, 12-month retrospective survey was conducted in 24 cities in six European countries -Finland, Germany, Italy, Romania, Spain and the United Kingdom. An estimated sample size of 2000 screened individuals per country was calculated in order to obtain a final sample of approximately 400 consumers per country (total N=2400 approximately). Per country, gender and age group quotas were set as follows: 300 adults (18 to 59 years) and 100 older adults (60-and-over years), with 30-50% male and 50-70% female. All individuals were screened by means of a brief questionnaire which recorded PFS usage in the preceding 12 months. Individuals were considered eligible for inclusion if they were over 18 years old and met either of the following specified criteria, intended to capture the different usage patterns of PFS consumers:

1) They had taken at least 1 PFS in the last 12 months, in an appropriate dose form at a minimum frequency of either:
    a) 1 daily dose for at least 2 consecutive or non-consecutive weeks, or
    b) 1 or more doses per week for at least 3 consecutive weeks or
    c) 1 or more doses per week for at least 4 consecutive or non-consecutive weeks
2) They had taken 2 or more different PFS, in an appropriate dose form, at a minimum frequency of 1 or more doses per week, with the sum of the usage period of the 2 or more products being equal to at least 4 weeks.

Instruments and variables

A short screening questionnaire was used to identify consumers who met the survey inclusion criteria; it consisted of six questions which allowed interviewers to identify eligible consumers, based on the product(s) used, the frequency and duration of use and the dose form. Eligible consumers subsequently completed a more detailed questionnaire on their PFS usage in the preceding 12 months, providing details of product/plant names, dosage forms, frequency of use, reasons for use, adverse effects, places and patterns of purchase and information sources on products. These questions were asked for each of up to a maximum of 5 different PFS used. In addition, respondents were asked to provide socio-demographic data including age, gender, level of education and employment status, as well as self-reported height and weight and further health-related lifestyle information.

Survey administration and data collection

Fieldwork and data collection for the cross-sectional survey were performed by the international market research company EFG, from May 2011 to September 2012. The duration of the fieldwork ensured that any seasonal variability in usage of products was captured. The survey protocols and instruments -training material, information sheet, informed consent, screening and usage questionnaires-, were initially developed in English by consensus amongst the research team, and subsequently translated into the respective languages in each of the survey countries. Pilot interviews were conducted in each participating country to assess the comprehension of the questions and to determine the time required to complete the survey.

In each participating country, trained interviewers systematically screened approximately 1000 individuals during the first three months of the survey, which allowed the estimation of the prevalence rate. Subsequently, screening and recruitment were conducted on a convenience basis. The recruited eligible consumers were interviewed face-to-face and the more detailed PFS usage questionnaire completed.

Data preparation and statistical analysis

All data from the completed surveys were entered into the statistical package SPSS for Windows v. 18 (IBM Corporation, Somers, NY, USA), which was also used for data analysis.

Following review of the completed interviews by the research team in each country, a database with botanical composition data for all PFS products reported was compiled for each country and then merged into a single database. Potential product duplicates between countries were not removed. Each product was coded for its botanical ingredients in scientific, English and local names and botanicals were coded after removing duplicates between countries. Additionally, each product was categorised as a single- or multi-botanical product. To indicate the certainty of the matching of products, a series of numerical codes were used, based on those used in the National Health and Nutrition Examination Survey 2005 – 2006 (NCHS 2009). Values ranged from 1-5, where “1” indicated an exact match, “2” a probable match, “3” a reasonable match, “4” a default match and “5” no match. Only products with certainty values 1 to 4 have been included in the analyses.

Respondent data were recorded in a separate database. A number of variables were created and/or recoded to facilitate reporting and analysis, including: 1) “education level”, defined as low, medium, and high; 2) “BMI”, which was calculated from self-reported weight and height, and for which WHO criteria (WHO 2013) were used to categorise individuals as underweight (BMI<18.5 kg/m^2), normal weight (BMI 18.5-<25 kg/m^2), overweight (BMI 25-<30 kg/m$^{2)}$ and obese (BMI $\geq$30 kg/m^2); 3) "physical activity", calculated using the short version of the IPAQ questionnaire (Craig *et al.* 2003) and defined as low, moderate or high.

Absolute frequencies and percentages for each of the variable categories were used to describe the qualitative nominal/ordinal and discrete quantitative survey data. In turn, all data have been stratified by gender, age range and country - also using absolute frequencies and percentages and 95% confidence intervals. When describing the association between two qualitative variables (nominal or ordinal), contingency tables were used. The continuous quantitative variables (e.g. BMI, alcohol) were recoded into categorical variables.

It is important to note that when reporting the main results of the survey, the unit of analysis varies depending on the variables used, i.e. for certain variables the unit is an individual respondent, however, given the potential intake of multiple supplements by one respondent, the unit of analysis may change to the supplement level. Furthermore, all results presented in the tables represent the analysis of raw data as opposed to data weighted by the population size. Data were not weighted because of the study methodology selected, whereby all country samples were very similar in size and included only PFS consumers.

Validation study

In order to validate the PFS usage questionnaire, a validation study was conducted in which the data collected using the survey instrument (questionnaire) were compared with data collected with a 30 to 180-day diary (used as the gold standard). The study was conducted in two of the PlantLIBRA consumer survey cities: Las Palmas de Gran Canaria (Spain) and Milan (Italy), where 48 and 49 consumers respectively were recruited using convenience sampling. The PFS usage questionnaire was completed by the respondents at the beginning and at the end of the 6-month period of the validation; during this time the consumers also completed the usage diary. Data from the last questionnaire and the diary were compared for concordance, and results are shown in Table 16, indicating a good agreement for product consumed, dose form and doses per day.

Table 16. Validation study results.

Variable	Concordance[a]	Milan		Las Palmas de Gran Canaria	
		n	%	n	%
Product used	Yes	47	95.9	48	100.0
	No	2	4.1	0	0.0
Dose form (pills, capsules, etc)	Yes	45	91.8	47	97.9
	No	4	8.2	1	2.1
Doses per day	Yes	45	91.8	38	79.2
	No	4	8.2	10	20.8

[a] Concordance between both methods: the PFS usage questionnaire and the 6-month usage diary.

2.3.3 Results

Characteristics of the PFS consumer sample

A final sample of 2359 consumers (those eligible and willing to participate) was recruited from 11783 screened individuals (Table 17). Due to different legal frameworks (different distribution of botanicals in food supplements and medicinal products), more individuals had to be screened in Finland in order to recruit the required 400 consumers. Table 17 also shows the sample used for the estimation of the usage prevalence rate. The estimated weighted overall PFS usage prevalence rate was 18.8% and per-country rates were as follows: Finland 9.6%, Germany 16.9%, Italy 22.7%, Romania 17.6%, Spain 18.0% and the United Kingdom 19.1%.

Survey respondents were recruited to fixed quotas for age and gender, which were achieved, with some differences within countries (Table 18). In Finland the proportion of adults aged 50-59 years was significantly higher (26.2%), whilst the opposite was true in Italy, where consumers in that age group constituted only 13.0% of adults. Romania had a significantly higher number of consumers in the youngest age group (30.5%), in contrast to Spain and the United Kingdom, where this age group represented only 9.5% and 9.0% of adult consumers, respectively. A significantly higher proportion of female consumers were recruited in Spain (56.7%) and in the United Kingdom marginally more males were recruited (50.3%). Across all countries, more than half of the participants (57.5%) were employed (Table 18), with the percentages slightly lower in Finland (50.9%) and in the United Kingdom (52.4%). The majority of participating consumers were educated to medium level (Table 18).

Respondents were asked a number of questions regarding health-related lifestyle factors (Table 19). Less than half of the consumers had never smoked (46.6%), less than one quarter were ex-smokers (23.1%) and less than one third were current smokers (30.3%). More than half of the total respondents (59.3%) had not consumed alcohol or had consumed it less than once daily; more than a tenth (12.6%) reported daily alcohol consumption.

The proportion of overweight and obese people in the survey was 49.8% (Table 19). Some significant differences in levels of physical activity were noted between countries. High levels of activity were reported by 85.5% of Romanian respondents compared to a value of 42.9% across all countries.

Most of the respondents (65.1%) reported not being regular consumers of food supplements other than PFS in the preceding 12 months, except for Finland (Table 19). The proportion of non-consumers varied from 20.7% in Finland to more than 80% in the United Kingdom and Italy. By contrast, in Finland 76.3 % of the individuals were regular consumers of food supplements. Over half of all respondents (59.5%) reported not having used CAM therapies/treatments in the past year. This is particularly the case in Italy (74.6%), Romania (80.8%) and the United Kingdom (92.6%).

Three quarters of consumers reported their health status as very good or good (75.5%), while 3.6% reported it as bad or very bad and 21.0 % as neither bad nor good (Table 19).

Between countries, more consumers reported their health status as very good or good in Romania (81.3%) and in the United Kingdom (81.1%) than in other countries; though conversely the highest proportion reporting their health status as bad or very bad was also in the United Kingdom (7.6%).

Table 17. Distribution of screened individuals, PFS consumers interviewed and prevalence sample by country and gender.

			Finland	Germany	Italy	Romania	Spain	United Kingdom	Total
Total contacts (n)	Total individuals screened for the survey	Males	1405	1031	907	795	811	830	5779
		Females	1379	1028	104 4	827	932	794	6004
	Total PFS consumers interviewed accepted	Males	193	197	187	199	174	191	1141
		Females	208	201	191	201	228	189	1218
Prevalence sample: systematically selected sample 1st three months of the Fieldwork (n)	Individuals screened	Males	486	564	439	502	551	454	2996
		Females	519	571	547	501	648	563	3349
	PFS consumers among Individuals screened	Males	33	90	99	95	55	65	437
		Females	71	111	156	124	133	144	739
PFS consumption prevalence (weighted) (%)			9.6	16.9	22.7	17.6	18.0	19.1	18.8

Table 18. PlantLIBRA's PFS consumer survey – socio-demographic sample characteristics, overall and by country.

Characteristics	Categories	All countries		Finland		Germany		Italy		Romania		Spain		United Kingdom	
		n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Gender	Male	1141	48.4 (46.4-50.4)	193	48.1 (43.2-53.0)	197	49.5 (44.6-54.4)	187	49.5 (44.4-54.5)	199	49.8 (44.8-54.7)	174	43.3 (38.4-48.1)	191	50.3 (45.2-55.3)
	Female	1218	51.6 (49.6-53.7)	208	51.9 (47.0-56.8)	201	50.5 (45.6-55.4)	191	50.5 (45.5-55.6)	201	50.3 (45.3-55.2)	228	56.7 (51.9-61.6)	189	49.7 (44.7-54.8)
Age	18-29 years	418	17.7 (16.2-19.3)	63	15.7 (12.1-19.3)	77	19.4 (15.5-23.2)	84	22.2 (18.0-26.4)	122	30.5 (26.0-35.0)	38	9.5 (6.6-12.3)	34	9.0 (6.1-11.8)
	30-39 years	445	18.9 (17.3-20.4)	65	16.2 (12.6-19.8)	57	14.3 (10.9-17.8)	88	23.3 (19.0-27.6)	65	16.3 (12.6-20.0)	101	25.1 (20.9-29.4)	69	18.2 (14.3-22.0)
	40-49 years	460	19.5 (17.9-21.1)	64	16.0 (12.4-19.6)	82	20.6 (16.6-24.6)	63	16.7 (12.9-20.4)	46	11.5 (8.4-14.6)	88	21.9 (17.8-25.9)	117	30.8 (26.1-35.4)
	50-59 years	441	18.7 (17.1-20.3)	105	26.2 (21.9-30.5)	80	20.1 (16.2-24.0)	49	13.0 (9.6-16.4)	67	16.8 (13.1-20.4)	76	18.9 (15.1-22.7)	64	16.8 (13.1-20.6)
	≥ 60 years	595	25.2 (23.5-27.0)	104	25.9 (21.6-30.2)	102	25.6 (21.3-29.9)	94	24.9 (20.5-29.2)	100	25.0 (20.8-29.3)	99	24.6 (20.4-28.8)	96	25.3 (20.9-29.6)
Education	Low	249	10.6 (9.3-11.8)	47	11.7 (8.6-14.9)	3	0.8 (0.0-1.6)	72	19.1 (15.1-23.0)	35	8.8 (6.0-11.5)	92	22.9 (18.8-27.0)	0	-
	Medium	1549	65.7 (63.6-67.6)	237	59.1 (54.3-63.9)	329	82.7 (78.9-86.4)	222	58.7 (53.8-63.7)	190	47.5 (42.6-52.4)	256	63.7 (59.0-68.4)	315	82.9 (79.1-86.7)
	High	561	23.8 (22.1-25.5)	117	29.2 (24.7-33.6)	66	16.6 (12.9-20.2)	84	22.2 (18.0-26.4)	175	43.8 (38.9-48.6)	54	13.4 (10.1-16.8)	65	17.1 (13.3-20.9)
Current employment status	Employed	1357	57.5 (55.5-59.5)	204	50.9 (46.0-55.8)	240	60.3 (55.5-65.1)	221	58.5 (53.5-63.4)	249	62.3 (57.5-67.0)	244	60.7 (55.9-65.5)	199	52.4 (47.3-57.4)
	Other groups [a]	1002	42.5 (40.9-44.5)	197	49.1 (44.2-54.0)	158	39.7 (34.9-44.5)	157	41.5 (36.6-46.5)	151	37.8 (33.0-42.5)	181	39.3 (34.5-44.1)	181	47.6 (42.6-52.7)

[a]. Other groups: Unemployed; Housework; Student; Retired; Disabled; and Other.

Table 19. PlantLIBRA's PFS consumer survey – health-related lifestyle sample characteristics, overall and by country.

Characteristics	Categories	All countries		Finland		Germany		Italy		Romania		Spain		United Kingdom	
		n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Regular use of non-PFS FS[ab]	No	1536	65.1 (63.2-67.0)	83	20.7 (16.7-24.7)	251	63.1 (58.3-67.8)	311	82.3 (78.4-86.1)	274	68.5 (63.9-73.1)	312	77.6 (73.5-81.7)	305	80.3 (76.3-84.3)
	Yes	767	32.5 (30.6-34.4)	306	76.3 (72.1-80.5)	122	30.7 (26.1-35.2)	63	16.7 (12.9-20.4)	112	28.0 (23.6-32.4)	89	22.1 (18.1-26.2)	75	19.7 (15.7-23.7)
	Not sure	56	2.4 (1.8-3.0)	12	3.0 (1.3-4.7)	25	6.3 (3.9-8.7)	4	1.1 (0.1-2.1)	14	3.5 (1.7-5.3)	1	0.3 (0.0-0.7)	0	-
Smoking habit	Never smoker	1100	46.6 (44.6-48.6)	182	45.4 (40.5-50.3)	183	46.0 (41.1-50.9)	181	47.9 (42.8-52.9)	214	53.5 (48.6-58.4)	177	44.0 (39.2-48.9)	163	42.9 (37.9-47.9)
	Former smoker	544	23.1 (21.4-24.8)	129	32.2 (27.6-36.8)	81	20.4 (16.4-24.3)	85	22.5 (18.3-26.7)	57	14.3 (10.8-17.7)	94	23.4 (19.2-27.5)	98	25.8 (21.4-30.2)
	Current smoker	715	30.3 (28.5-32.2)	90	22.4 (18.4-26.5)	134	33.7 (29.0-38.3)	112	29.6 (25.0-34.2)	129	32.3 (27.7-36.8)	131	32.6 (28.0-37.2)	119	31.3 (26.7-36.0)
Self-reported health status	Very good	353	15.0 (13.5-16.4)	81	20.2 (16.3-24.1)	49	12.3 (9.1-15.5)	22	5.8 (3.5-8.2)	80	20.0 (16.1-23.9)	49	12.2 (9.0-15.4)	72	19.0 (15.0-22.9)
	Good	1427	60.5 (58.5-62.5)	225	56.1 (51.3-61.0)	220	55.3 (50.4-60.2)	243	64.3 (59.5-69.1)	245	61.3 (56.5-66.0)	258	64.2 (59.5-68.9)	236	62.1 (57.2-67.0)
	Neither bad nor good	496	21.0 (19.4-22.7)	77	19.2 (15.3-23.1)	111	27.9 (23.5-32.3)	111	29.4 (24.8-34.0)	73	18.3 (14.5-22.0)	81	20.2 (16.2-24.1)	43	11.3 (8.1-14.5)
	Bad	70	3.0 (2.3-3.7)	16	4.0 (2.1-5.9)	18	4.5 (2.5-6.6)	2	0.5 (0.0-1.3)	2	0.5 (0.0-1.2)	14	3.5 (1.7-5.3)	18	4.7 (2.6-6.9)
	Very bad	13	0.6 (0.3-0.9)	2	0.5 (0.0 - 1.2)	0	-	0	-	0	-	0	-	11	2.9 (1.2-4.6)
CAM[c] usage	Yes	947	40.1 (38.2-42.1)	223	55.6 (50.7-60.5)	204	51.3 (46.3-56.2)	96	25.4 (21.0-29.8)	77	19.3 (15.4-23.1)	319	79.4 (75.4-83.3)	28	7.4 (4.7-10.0)
	No	1412	59.9 (57.9-61.8)	178	44.4 (39.5-49.3)	194	48.7 (43.8-53.7)	282	74.6 (70.2-79.0)	323	80.8 (76.9-84.6)	83	20.7 (16.7-24.6)	352	92.6 (90.0-95.3)
Alcohol consumption	0-<1 times/day	1398	59.3 (57.3-61.3)	281	70.1 (65.6-74.6)	245	61.6 (56.8-66.3)	116	30.7 (26.0-35.3)	232	58.0 (53.2-62.8)	291	72.4 (68.0-76.8)	233	61.3 (56.4-66.2)
	≥ 1 times/day	296	12.6 (11.2-13.9)	13	3.2 (1.5-5.0)	27	6.8 (4.3-9.3)	156	41.3 (36.3-46.2)	9	2.3 (0.8-3.7)	46	11.4 (8.3-14.6)	45	11.8 (8.6-15.1)
	Not sure	614	26.0 (24.3-27.8)	107	26.7 (22.4-31.0)	126	31.7 (27.1-36.2)	106	28.0 (23.5-32.6)	159	39.8 (35.0-44.6)	65	16.2 (12.6-19.8)	102	26.8 (22.4-31.3)
BMI[d] categories	Underweight	69	2.9 (2.4-3.6)	9	2.2 (0.8-3.7)	4	1.0 (0.0-2.0)	12	3.2 (1.4-4.9)	20	5.0 (2.9-7.1)	6	1.5 (.3-2.7)	18	4.7 (2.6-6.9)
	Normal weight	1116	47.3 (45.3-49.3)	188	46.9 (42.0-51.8)	198	49.7 (44.8-54.7)	246	65.1 (60.3-69.9)	184	46.0 (41.1-50.9)	169	42.0 (37.2-46.9)	131	34.5 (29.7-39.3)
	Overweight	818	34.7 (32.8-36.6)	147	36.7 (31.9-41.4)	159	40.0 (35.1-44.8)	98	25.9 (21.5-30.4)	142	35.5 (30.8-40.2)	155	38.6 (33.8-43.3)	117	30.8 (26.1-35.4)
	Obesity	356	15.1 (13.7-16.5)	57	14.2 (10.8-17.6)	37	9.3 (6.4-12.2)	22	5.8 (3.5-8.2)	54	13.5 (10.2-16.9)	72	17.9 (14.2-21.7)	114	30.0 (25.4-34.6)
Physical activity[e]	Low	436	18.5 (16.9-20.1)	53	13.2 (9.9-16.5)	87	21.9 (17.8-25.9)	141	37.3 (32.4-42.2)	5	1.3 (0.2-2.3)	43	10.7 (7.7-13.7)	107	28.2 (23.6-32.7)
	Moderate	909	38.5 (36.6-40.5)	156	38.9 (34.1-43.7)	139	34.9 (30.2-39.6)	191	50.5 (45.5-55.6)	53	13.3 (9.9-16.6)	234	58.2 (53.4-63.0)	136	35.8 (31.0-40.6)
	High	1012	42.9 (40.9-44.9)	192	47.9 (43.0-52.8)	171	43.0 (38.1-47.8)	45	11.9 (8.6-15.2)	342	85.5 (82.1-89.0)	125	31.1 (26.6-35.6)	137	36.1 (31.2-40.9)

[a] ***Question asked:*** Other than PLANT FOOD SUPPLEMENT, have you taken any of the following supplements on a regular basis in the last 12 months? (mark all that apply). ***Possible responses:*** Vitamins (A, B, D, E, etc.); Minerals (eg. potassium, calcium); Amino acids; Enzymes (eg. lactase); Prebiotics (eg. oligosaccharides, fibre); Probiotics (eg. bifidobacteria, yeasts); Fatty acids (eg. fish oil); Other.

[b] FS= Food supplements.

[c] CAM=Complementary and Alternative Medicine, including : Acupuncturist; Chiropractor; Homeopath; Herbalist; Massage therapist; Traditional/faith healer; Reflexologist; Recognised treatment i.e. not "alternative"; Esoteric treatment; and “Cannot be classified”.

[d] BMI= Body Mass Index; WHO categories (WHO 2013).

[e] IPAQ categories (Craig *et al.* 2003).

PFS usage patterns

Overall, products are most often taken “periodically” (37.3%) with respondents also reporting using PFS when experiencing a “flare up or worsening of a condition” (22.2%) (Table 20). Products are also used on a more “sporadic basis” (19.8%) and on “other non-specified occasions” (17.8%). Both men and women reported taking products on a periodic basis (39.3%, 35.6%) and this was also true for both age groups (Table 20). Periodic use was reported significantly more often in Finland (46.2%), Germany (50.7%), Italy (41.3%) and Romania (41.8%), but in Spain, “another reason” was most reported (46.0%) and in the United Kingdom, sporadic use (34.8%) was significantly higher than any other reason as to when products were used (Table 21).

Table 20. PlantLIBRA's PFS consumer survey – PFS usage patterns, per product used by a respondent, overall and by gender and age group.

	Total (n=2874)		Gender				Age group			
			Male (n=1358)		Female (n=1516)		18-59 years (n=2131)		≥60 years (n=743)	
	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
I took it whenever/sporadically	568	19.8 (18.3-21.2)	280	20.6 (18.5-22.8)	288	19.0 (17.0-21.0)	437	20.5 (18.8-22.2)	131	17.6 (14.9-20.4)
I take it periodically, during those times only	1072	37.3 (35.5-39.1)	533	39.3 (36.7-41.9)	539	35.6 (33.1-38.0)	827	38.8 (36.7-40.9)	245	33.0 (29.6-36.46)
I took it when I had a flare up/worsening of condition	638	22.2 (20.7-23.7)	278	20.5 (18.3-22.6)	360	23.8 (21.6-25.9)	451	21.2 (19.4-22.9)	187	25.2 (22.1-28.3)
Other reason	512	17.8 (16.4-19.2)	224	16.5 (14.5-18.5)	288	19.0 (17.0-21.0)	353	16.6 (15.0-18.1)	159	21.4 (18.5-24.4)
Not sure	84	2.9 (2.3-3.5)	43	3.2 (2.2-4.1)	41	2.7 (1.9-3.5)	63	3.0 (2.2-3.7)	21	2.8 (1.6-4.0)

Questions asked. During the last 12 months, in what months have you taken this supplement? (mark all that apply). ***Possible responses:*** Jan, Feb, Mar, Apr, May, June, July, Aug, Sep, Oct, Nov, Dec, All year round; Why did you decide to take this supplement in the months stated? (one answer only). ***Possible responses:*** I took it whenever/sporadically; I take it periodically, during those times only; When I had a flare up/worsening of condition; Other reason; Not sure.

Table 21. PlantLIBRA's PFS consumer survey – PFS usage patterns, per product used by a respondent, overall and by country.

	Finland (n=665)		Germany (n=446)		Italy (n=417)		Romania (n=464)		Spain (n=465)		United Kingdom (n=417)	
	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
I took it whenever/sporadically	83	12.5 (10.0-15.0)	102	22.9 (19.0-26.8)	73	17.5 (13.9-21.2)	60	12.9 (9.9-16.0)	105	22.6 (18.8-26.4)	145	34.8 (30.2-39.4)
I take it periodically, during those times only	307	46.2 (42.4-50.0)	226	50.7 (46.0-55.3)	172	41.3 (36.5-46.0)	194	41.8 (37.3-46.3)	68	14.6 (11.4-17.8)	105	25.2 (21.0-29.4)
I took it when I had a flare up/worsening of condition	126	19.0 (16.0-21.9)	89	20.0 (16.2-23.7)	128	30.7 (26.3-35.1)	117	25.2 (21.3-29.2)	75	16.1 (12.8-19.5)	103	24.7 (20.6-28.8)
Other reason	140	21.1 (18.0-24.2)	26	5.8 (3.7-8.0)	32	7.7 (5.1-10.2)	51	11.0 (8.1-13.8)	214	46.0 (41.5-50.6)	49	11.8 (8.7-14.9)
Not sure	9	1.4 (0.5-2.2)	3	0.7 (0.0-1.4)	12	2.9 (1.3-4.5)	42	9.1 (6.4-11.7)	3	0.7 (0.0-1.4)	15	3.6 (1.8-5.4)

Questions asked. During the last 12 months, in what months have you taken this supplement? (mark all that apply) ***Possible responses:*** Jan, Feb, Mar, Apr, May, June, July, Aug, Sep, Oct, Nov, Dec, All year round; Why did you decide to take this supplement in the months stated? (one answer only) ***Possible responses:*** I took it whenever/sporadically; I take it periodically, during those times only; When I had a flare up/worsening of condition; Other reason; Not sure.

PFS products used

Respondents reported a total of 1288 products across the six countries. At individual country level, the highest numbers of different PFS were used in Italy (289) and Spain (284); in the United Kingdom, the number of different PFS was approximately half that of the other countries (Table 22). The number of different botanical ingredients was 491, with the maximum number of different botanicals contained in a single product being 46 and present in a German product. The United Kingdom differed from the other countries as the products reported contained a lower number of botanical ingredients (maximum 8).

In terms of the number of products used, 83.7% of all consumers reported taking one product in the preceding 12 months, with 12.3% taking two products and 4.0% using more than two products (Table 23). Generally this pattern was similar for both men and women and across the age groups, although those over 60 did report a significantly higher use of two or more products than those under 60 (19.5% vs. 15.2%) (Table 23). At country level (Table 24), some significant differences were noted: in Finland, the percentage of consumers using two or more products was significantly higher than in all other countries (40.2%).

Overall 51.5% of consumers used a single-botanical product and 32.3% used one multi-botanical product (Table 23). There were no significant differences between males and females in this usage pattern, but consumers aged over 60 used less multi-botanical products than those aged 18-59 (27.7% and 33.8% respectively) (Table 23). Overall, fewer consumers reported using two or more single-botanical products (4.4%) and two or more single- and multi-botanical products (11.9%) (Table 23).

There were some significant differences across countries in the type of products consumed (Table 24). In the six countries, the values for single-botanical products range from 84.5% (the United Kingdom) to 20.5% (Finland). Usage of multi-botanical products was reported in all countries, with the lowest proportion (7.1%) reported in the United Kingdom (Table 24). The use of two or more single-botanical products was low in all countries as was the usage of two or more single- and multi-botanical products. Finland was an exception to the latter, with 38.2% of respondents taking multiple products (Table 24).

The most common dose forms used (Table 25) are capsules (38.3%) and pills/tablets/lozenges (36.8%). No significant difference was observed in relation to gender or age (Table 25). Across the six countries (Table 26), solid forms are generally most popular, although capsules were used less frequently in Romania (17.7%). Liquid forms were less common in the United Kingdom (8.2%) and Germany (9.9%), but more common in Finland (26.2%) and Italy (26.4%) (Table 26).

Table 22. PlantLIBRA's PFS consumer survey – Characteristics of PFS reported by respondents.

	Total	Finland	Germany	Italy	Romania	Spain	United Kingdom
Number of products	1288	213	190	289	196	284	116
Number of botanicals	491	196	191	222	219	218	47
Number of manufacturers	449	69	99	106	61	97	17
Maximum number of ingredients per product	46	23	46	20	39	30	8

Table 23. PlantLIBRA's PFS consumer survey – number and type of products taken, overall distribution and by gender and age group.

		Total)		Gender				Age group			
		(n=2359)		Male (n=1141)		Female (n=1218)		18-59 years (n=1764)		≥60 years (n=595)	
		n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Number of products taken	1 product	1975	83.7 (82.2-85.2)	980	85.9 (83.9-87.9)	995	81.7 (79.5-83.9)	1496	84.8 (83.1-86.5)	479	80.5 (77.3-83.7)
	2 products	289	12.3 (10.9-13.6)	123	10.8 (9.0-12.6)	166	13.6 (11.7-15.6)	196	11.1 (9.6-12.6)	93	15.6 (12.7-18.6)
	>2 products	95	4.0 (3.2-4.8)	38	3.3 (2.3-4.4)	57	4.7 (3.5-5.9)	72	4.1 (3.2-5.0)	23	3.9 (2.3-5.4)
Product type	1 single-botanical	1214	51.5 (49.5-53.5)	606	53.1 (50.2-56.0)	608	49.9 (47.1-52.7)	900	51.0 (48.7-53.4)	314	52.8 (48.8-56.8)
	1 multi -botanical	761	32.3 (30.4-34.2)	374	32.8 (30.1-35.5)	387	31.8 (29.2-34.4)	596	33.8 (31.6-36.0)	165	27.7 (24.1-31.3)
	2 or more single-botanical	104	4.4 (3.6-5.2)	45	3.9 (2.8-5.1)	59	4.8 (3.6-6.1)	72	4.1 (3.2-5.0)	32	5.4 (3.6-7.2)
	2 or more single- and multi-botanical	280	11.9 (10.6-13.2)	116	10.2 (8.4-11.9)	164	13.5 (11.6-15.4)	196	11.1 (9.6-12.6)	84	14.1 (11.3-16.9)

Table 24. PlantLIBRA's PFS consumer survey – number and type of products taken, by country.

		Finland (n=401)		Germany (n=398)		Italy (n=378)		Romania (n=400)		Spain (n=402)		United Kingdom (n=380)	
		n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Number of products taken	1 product	240	59.9 (55.1-64.7)	351	88.2 (85.0-91.4)	341	90.2 (87.2-93.2)	350	87.5 (84.3-90.8)	345	85.8 (82.4-89.2)	348	91.6 (88.8-94.4)
	2 products	93	23.2 (19.1-27.3)	45	11.3 (8.2-14.4)	34	9.0 (6.1-11.9)	40	10.0 (7.1-12.9)	48	11.9 (8.8-15.1)	29	7.6 (5.0-10.3)
	>2 products	68	17.0 (13.3-20.6)	2	0.5 (0.0-1.2)	3	0.8 (0.0-1.7)	10	2.5 (1.0-4.0)	9	2.2 (0.8-3.7)	3	0.8 (0.0-1.7)
Product type	1 single-botanical	82	20.5 (16.5-24.4)	172	43.2 (38.3-48.1)	176	46.6 (41.5-51.6)	251	62.8 (58.0-67.5)	212	52.7 (47.9-57.6)	321	84.5 (80.8-88.1)
	1 multi -botanical	158	39.4 (34.6-44.2)	179	45.0 (40.1-49.9)	165	43.7 (38.6-48.7)	99	24.8 (20.5-29.0)	133	33.1 (28.5-37.7)	27	7.1 (4.5-9.7)
	2 or more single-botanical	8	2.0 (0.6-3.4)	12	3.0 (1.3-4.7)	13	3.4 (1.6-5.3)	20	5.0 (2.9-7.1)	26	6.5 (4.1-8.9)	25	6.6 (4.1-9.1)
	2 or more single- and multi-botanical	153	38.2 (33.4-42.9)	35	8.8 (6.0-11.6)	24	6.4 (3.9-8.8)	30	7.5 (4.92-10.1)	31	7.7 (5.1-10.3)	7	1.8 (0.5-3.2)

Table 25. PlantLIBRA's PFS consumer survey – PFS dose forms used, per product used by a respondent, overall and by gender and age group.

Dose forms	Total		Gender				Age group			
	(n=2874)		Male (n=1358)		Female (n=1516)		18-59 years (n=2131)		≥60 years (n=743)	
	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Capsules[a]	1101	38.3 (36.5-40.1)	522	38.4 (35.9-41.0)	579	38.2 (35.8-40.6)	844	39.6 (37.5-41.7)	257	34.6 (31.2-38.0)
Pills/tablets/lozenges	1057	36.8 (35.0-38.5)	498	36.7 (34.1-39.2)	559	36.9 (34.4-39.3)	765	35.9 (33.8-37.9)	292	39.3 (35.8-42.8)
Liquid[b]	513	17.9 (16.5-19.3)	238	17.5 (15.5-19.6)	275	18.1 (16.2-20.1)	374	17.6 (15.9-19.2)	139	18.7 (15.9-21.5)
Ampoules	104	3.6 (2.9-4.3)	53	3.9 (2.9-4.9)	51	3.4 (2.5-4.3)	75	3.5 (2.7-4.3)	29	3.9 (2.5-5.3)
Other[c]	99	3.4 (2.8-4.1)	47	3.5 (2.5-4.4)	52	3.4 (2.5-4.4)	73	3.4 (2.7-4.2)	26	3.5 (2.2-4.8)

Question asked. And in which form do you usually take it? (mark the applicable form). *Possible responses*: Pills/tablets/lozenges; Softgel capsules/pearls; Hard capsules; Liquid (extract/syrup/drops); Sachets/packets; Ampoules; Other (specify); Not sure.
[a].Capsules: softgels/pearls/hard capsules
[b].Liquid: extract/syrups/drops
[c].Other: Powders, Sachets/Packets, Bars and "Not sure".

Table 26. PlantLIBRA's PFS consumer survey – PFS dose forms, per product used by a respondent, by country.

Dose forms	Finland (n=665)		Germany (n=446)		Italy (n=417)		Romania (n=464)		Spain (n=465)		United Kingdom (n=417)	
	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Capsules[a]	206	31.0 (27.5-34.5)	225	50.5 (45.8-55.1)	144	34.5 (30.0-39.1)	82	17.7 (14.2-21.2)	250	53.8 (49.2-58.3)	194	46.5 (41.7-51.3)
Pills/tablets/lozenges	261	39.3 (35.5-43.0)	154	34.5 (30.1-39.0)	126	30.2 (25.8-34.6)	234	50.4 (45.9-55.0)	98	21.1 (17.4-24.8)	184	44.1 (39.4-48.9)
Liquid[b]	174	26.2 (22.8-29.5)	44	9.9 (7.1-12.6)	110	26.4 (22.1-30.6)	82	17.7 (14.2-21.2)	69	14.8 (11.6-18.1)	34	8.2 (5.5-10.8)
Ampoules	0	-	0	-	13	3.1 (1.5-4.8)	47	10.1 (7.4-12.9)	44	9.5 (6.8-12.1)	0	-
Other[c]	24	3.6 (2.2-5.0)	23	5.2 (3.1-7.2)	24	5.8 (3.5-8.0)	19	4.1 (2.3-5.9)	4	0.9 (0.1-1.7)	5	1.2 (0.2-2.2)

Question asked. And in which form do you usually take it? (mark the applicable form). *Possible responses*: Pills/tablets/lozenges; Softgel capsules/pearls; Hard capsules; Liquid (extract/syrup/drops); Sachets/packets; Ampoules; Other (specify); Not sure.
[a].Capsules: softgels/pearls/hard capsules.
[b].Liquid: extract/syrups/drops.
[c].Other: Powders, Sachets/Packets, Bars and "Not sure".

Botanicals used

A total of 491 botanicals -used in at least one PFS- were reported across the six participating countries. An overview of all the reported botanicals -clustered by intervals of frequency of intake (number of consumers ranging from 194 to 5)- is shown in Table 27. Based on the survey results, the eleven most frequently used botanicals (numbers of consumers ranging from 194 to 100) in descending order are *Ginkgo biloba* (ginkgo), *Oenothera biennis* (evening primrose), *Cynara scolymus* (artichoke), *Panax ginseng* (ginseng), *Aloe vera* (aloe), *Foeniculum vulgare* (fennel), *Valeriana officinalis* (valerian), *Glycine max* (soybean), *Melissa officinalis* (lemon balm), *Echinacea purpurea* (echinacea) and *Vaccinium myrtillus* (blueberry) (Table 27).

Table 28 shows the overall unweighted ranking of botanicals, 1-40, according to the number of consumers, in decreasing order. Table 28 also shows that when unweighted overall data are stratified by gender, only slight differences between men and women become evident and only *Glycine max* (soybean) was used significantly more by women than by men (Table 28).

When the overall top-40 botanical data are stratified by age groups, slight differences become evident. In the group of 18-59 year-olds, the most frequently used botanicals comply with the overall data just differing in the ranking, with *Oenothera biennis* (evening primrose) being the most frequently used botanical (Table 28). In the group of 60+ year-old a stronger shift can be observed (Table 28). Although *Ginkgo biloba* (ginkgo) is still the most reported botanical -as in the overall ranking- other botanicals are frequently used by that age group. *Harpagophytum procumbens* (devil´s claw), *Vaccinium myrtillus* (blueberry) and *Allium sativum* (garlic) are within the most frequently reported botanicals, whereas *Glycine max* (soybean), *Melissa officinalis* (lemon balm) and *Echinacea purpurea* (echinacea) do not appear in the top 10 ranking.

Cross-country differences emerge when considering the overall top-40 botanicals more frequently present in PFS products in each of the individual six countries (Table 29). In the Finnish sample, products containing *Glycine max* (soybean) are the most frequently used, followed by those containing *Echinacea angustifolia and purpurea* (echinacea). German consumers reported *Ginkgo biloba* (ginkgo), *Cynara scolymus* (artichoke) and *Olea europea* (olive) as the most frequently used botanicals; whilst in Romania, *Ginkgo biloba* (ginkgo) was also the ingredient most frequently indicated, followed by *Aloe vera* (aloe) and *Panax ginseng* (ginseng). Amongst Italian consumers, *Aloe vera* (aloe) was the most frequently used botanical, followed by *Foeniculum vulgare* (fennel) and *Valeriana officinalis* (valerian). In Spain, PFS containing *Cynara scolymus* (artichoke) were the most frequently used products, followed by those containing *Valeriana officinalis* (valerian) and *Equisetum arvense* (horsetail). In the United Kingdom, *Oenothera biennis* (evening primrose) was by far the most frequently reported botanical ingredient, followed by *Panax ginseng* (ginseng) and *Hypericum perforatum* (St. John´s wort). In addition, there is a great variation in the ranking of consumed botanicals among countries.

Table 27. PlantLIBRA's PFS consumer survey – botanicals used by at least 5 respondents, ordered by the "n of respondents".

Used by n≥75 respondents		Used by n≥40-<75 respondents		Used by n ≥20-<40 respondents		Used by n≥5-<20 respondents	
n	Botanical(s)	n	Botanical(s)	n	Botanical(s)	n	Botanical(s)
194	*Ginkgo biloba; Oenothera biennis*	74	*Glycyrrhiza glabra*	38	*Cichorium intybus; Malus pumila*	19	*Achillea millefolium; Arctium lappa; Centella asiatica; Punica granatum; Raphanus sativus; Pyrus communis*
177	*Cynara scolymus*	72	*Mentha piperita; Paullinia cupana*	37	*Curcuma longa*	18	*Artemisia absinthium; Pollen; Lecithin*
170	*Panax ginseng*	71	*Malpighia glabra*	36	*Ananas comosus*	17	*Betula pubescens; Spirulina spec.; Vegetable charcoal;*
145	*Aloe vera*	70	*Oenothera spec.*	35	*Daucus carota; Glycine spec.*	16	*Origanum majorana; Ruscus aculeatus;Terminalia chebula*
131	*Foeniculum vulgare ssp*	69	*Silybum marianum*	34	*Myristica fragrans*	15	*Citrus paradise; Eschscholzia californica; Medicago sativa; Picea spec.; Vaccinium oxycoccus; Inulin*
128	*Valeriana officinalis*	66	*Citrus limon; Matricaria chamomilla*	33	*Crataegus monogyna; Cucurbita spec.; Dianthus spec.; Monascus purpureus*	14	*Althaea officinalis; Cuminum cyminum; Eryngium planum; Laminaria digitata; Rhamnus purshianus; Trigonella foenum-graecum; Zea mays*
103	*Glycine max ; Melissa officinalis*	64	*Urtica dioica*	32	*Petroselinum crispum; Vaccinium macrocarpon*	13	*Chelidonium majus; Dioscorea villosa; Gossypium spec.; Hyssopus officinalis; Lactuca sativa; Origanum vulgare; Orthosiphon stamineus; Piper nigrum; Theobroma cacao; Trifolium pratense; Uncaria tomentosa; Lycopene; Equisetum spec.; Valeriana spec.*
102	*Echinacea purpurea*	63	*Thymus vulgaris*	31	*Coriandrum sativum; Echinaca spec.; Elettaria cardamomum; Prunus domestica*	12	*Asparagus officinalis; Azadirachta indica; Cassia occidentalis; Eucalyptus globulus; Tagetes erecta; Mentha spec.; Smilax officinalis; Xanthium spinosum*
100	*Vaccinium myrtillus;*	61	*Salvia officinalis*	30	*Cymbopogon citratus; Rhodiola rosea;*	11	*Abies alba; Artemisia abrotanum; Cetraria islandica; Cinnamomum camphora; Ilex paraguariensis; Laurus nobilis; Nasturtium officinale; Salix alba; Tilia spec.; Fraxinus excelsior; Gentiana asclepiadea; Triticum aestivum*
89	*Camellia sinensis; Zingiber officinale*	60	*Cassia senna; Rosmarinus officinalis*	29	*Calendula officinalis*	10	*Aegle marmelos; Aquilegia spec.; Armoracia rusticana; Brassica oleracea ssp.; Cheilocostus speciosus; Kaempferia galangal; Lepidium meyenii; Pimenta dioica; Populus nigra; Potentilla aurea; Santalum spec.; Sida cordifolia; Terminalia arjuna; Thymus serpyllum; Rubus fruticosus; Carlina acaulis; Centaurium spec.; Ganoderma lucidum; Tamarix gallica; Ceratonia siliqua*
88	*Pimpinella anisum*	59	*Hypericum perforatum; Lavandula angustifolia*	28	*Eleutherococcus senticosus; Fucus vesiculosus; Plantago ovate; Solanum lycopersicum; Spirulina platensis; Saccharomyces cerevisiae*	9	*Aesculus hippocastanum; Aloe ferox; Berberis aristata; Brassica oleracea var. botrytis; Capparis spinosa; Capsicum annuum var. annuum; Hieracium pilosella; Opuntia ficus-indica; Serenoa repens; Solanum nigrum; Tribulus terrestris; Melissa spec.*
87	*Vitis vinifera*	58	*Carum carvi*	27	*Citrus aurantium*	8	*Allium cepa; Apium graveolens; Boswellia serrate; Coffea spec.; Euterpe oleracea; Fumaria officinalis; Griffonia simplicifolia; Illicium verum; Malva sylvestris; Prunus armeniaca; Raphanus sativus convar. Sativus; Solidago virgaurea; Tamarindus indica; Carotene; ; Garcinia cambogia; Soy lecithin*
81	*Taraxacum officinale*	53	*Ribes nigrum*	26	*Schisandra chinensis; Flavonoids; Syzygium aromaticum*	7	*Acorus calamus; Angelica sinensis; Ascophyllum nodosum; Elymus repens; Ficus carica; Hamamelis virginiana; Phaseolus vulgaris; Prunus persica; Rheum spec.; Lutein; Capsicum annuum; Fraxinus spec.; Chamomile Eng; Violeta tricolor;*
79	*Echinacea angustifolia*	52	*Oryza sativa;*	25	*Angelica archangelica; Beta vulgaris ssp.vulgaris var. conditiva; Citrus sinensis; Juniperus communis; Peumus boldus*	6	*Brassica nigra; Brassica oleracea convar. acephala; Capsicum frutescens; Carthamus tinctorius; Cordyceps sinensis; Dioscorea spec.; Drosera rotundifolia; Echinacea pallida; Emblica officinalis; Fallopia japonica; Hedera spec.; Nigella sativa; Plantago psyllium; Satureja hortensis; Tilia platyphyllos; Hibiscus rosa-sinensis; Cirsium spec.; Fragaria spec.; Viola tricolor; Lavandula spec.; Fructooligosaccharides*
78	*Allium sativum Passiflora incarnata;*	48	*Hippophae rhamnoides*	23	*Borago officinalis; Gentiana lutea; Helianthus annuus; Ocimum basilicum; Panicum miliaceum; Pinus spec.*	5	*Aloe spec.; Alpinia galanga; Chamaemelum nobile; Coffea arabica; Cola acuminata; Cyamopsis tetragonoloba; Equisetum telmateia; Fagopyrum esculentum; Hibiscus sabdariffa; Pinus pinaster; Pinus sylvestris; Thymus spec.; Undaria pinnatifida; Withania somnifera; Isoflavones; Arecaceae spec.; Fallopia multiflora*
77	*Linum usitatissimum*	46	*Triticum spec.*	22	*Plantago lanceolata; Rhamnus frangula; Vaccinium vitis-idaea*		
76	*Equisetum arvense*	43	*Rosa canina; Cinnamomum spec.*	21	*Carica papaya; Cinnamomum verum; Crataegus spec.; Hordeum vulgare; Polygonum aviculare; Saccharum officinarum; Spinacia oleracea*		
75	*Harpagophytum procumbens; Olea europaea*	42	*Sambucus nigra*	20	*Algae; Avena sativa; Betula spec.; Fiilipendula ulmaria; Humulus lupulus*		

Table 28. PlantLIBRA's PFS consumer survey – distribution of the overall top-40 botanicals' reported consumption and the ranking of these botanicals when stratified by gender and age group.

	All consumers			Gender						Age group					
Botanicals				Male			Female			18-59 years			≥60 years		
	Rank[a]	n	% (95 % CI)	Rank[b]	n	% (95 % CI)	Rank[b]	n	% (95 % CI)	Rank[b]	n	% (95 % CI)	Rank[b]	n	% (95 % CI)
Ginkgo biloba	1	194	8.2 (7.1-9.3)	1	107	9.4 (7.7-11.0)	3	87	7.1 (5.7-8.6)	2	135	7.7 (6.4-8.9)	1	59	9.9 (7.5-12.3)
Oenothera biennis	2	194	8.2 (7.1-9.3)	3	85	7.5 (5.9-8.9)	1	109	9.0 (7.4-10.5)	1	145	8.2 (6.9-9.5)	2	49	8.2 (6.0-10.4)
Cynara scolymus	3	173	7.3 (6.3-8.4)	5	73	6.4 (5.0-7.8)	2	100	8.2 (6.7-9.7)	4	128	7.3 (6.1-8.4)	4	45	7.6 (5.4-9.6)
Panax ginseng	4	167	7.1 (6.0-8.1)	2	94	8.2 (6.6-9.8)	5	73	6.0 (4.7-7.3)	3	133	7.5 (6.3-8.7)	6	34	5.7 (3.9-7.5)
Aloe vera	5	145	6.2 (5.2-7.1)	4	80	7.0 (5.5-8.5)	7	65	5.3 (4.1-6.6)	5	99	5.6 (4.5-6.7)	3	46	7.7 (5.6-9.8)
Foeniculum vulgare ssp.	6	132	5.6 (4.7-6.5)	7	59	5.2 (3.9-6.4)	4	73	6.0 (4.7-7.3)	6	99	5.6 (4.5-6.7)	7	33	5.6 (3.7-7.3)
Valeriana officinalis	7	125	5.3 (4.4-6.2)	6	62	5.4 (4.1-6.7)	8	63	5.2 (3.9-6.4)	7	97	5.5 (4.4-6.5)	9	28	4.7 (3.0-6.4
Glycine max	8	103	4.4 (3.5-5.2)	24	34	3.0 (2.0-3.9)	6	69	5.7 (4.4-6.9)	10	81	4.6 (3.6-5.5)	14	22	3.7 (2.2-5.2)
Melissa officinalis	9	103	4.4 (3.5-5.2)	8	53	4.7 (3.4-5.8)	10	50	4.1 (3.0-5.2)	9	82	4.7 (3.7-5.6)	17	21	3.5 (2.1-5.0)
Echinacea purpurea	10	102	4.3 (3.5-5.1)	12	43	3.8 (2.7-4.8)	9	59	4.8 (3.6-6.0)	8	83	4.7 (3.7-5.7)	21	19	3.2 (1.8-4.6)
Vaccinium myrtillus	11	100	4.2 (3.4-5.1)	9	53	4.7 (3.4-5.8)	13	47	3.9 (2.8-4.9)	12	71	4.0 (3.1-4.9)	8	29	4.9 (3.1-6.6)
Pimpinella anisum	12	89	3.8 (3.0-4.5)	11	47	4.1 (3.0-5.2)	21	42	3.5 (2.4-4.4)	16	65	3.7 (2.8-4.5)	11	24	4.0 (2.5-5.6)
Zingiber officinale	13	89	3.8 (3.0-4.5)	10	53	4.7 (3.4-5.8)	29	36	3.0 (2.0-3.9)	15	66	3.7 (2.9-4.6)	13	23	3.9 (2.3-5.4)
Camellia sinensis	14	87	3.7 (2.9-4.5)	17	39	3.4 (2.4-4.4)	11	48	3.9 (2.9-5.0)	11	72	4.1 (3.2-5.0)	33	15	2.5 (1.3-3.7)
Vitis vinifera	15	87	3.7 (2.9-4.5)	16	41	3.6 (2.5-4.6)	15	46	3.8 (2.7-4.8)	13	71	4.0 (3.1-4.9)	32	16	2.7 (1.4-4.0)
Taraxacum officinale	16	80	3.4 (2.7-4.1)	21	36	3.2 (2.1-4.1)	17	44	3.6 (2.6-4.6)	17	65	3.7 (2.8-4.5)	34	15	2.5 (1.3-3.7)
Echinacea angustifolia	17	79	3.4 (2.6-4.1)	23	34	3.0 (2.0-3.9)	16	45	3.7 (2.6-4.7)	20	60	3.4 (2.6-4.2)	20	19	3.2 (1.8-4.6)
Passiflora incarnata	18	78	3.3 (2.6-4.0)	30	30	2.6 (1.7-3.5)	12	48	3.9 (2.9-5.0)	19	61	3.5 (2.6-4.3)	30	17	2.9 (1.5-4.2)
Linum usitatissimum	19	77	3.3 (2.6-4.0)	13	43	3.8 (2.7-4.8)	33	34	2.8 (1.9-3.7)	22	56	3.2 (2.4-4.0)	16	21	3.5 (2.1-5.0)
Equisetum arvense	20	76	3.2 (2.5-3.9)	19	37	3.2 (2.2-4.2)	23	39	3.2 (2.2-4.2)	23	55	3.1 (2.3-3.9)	15	21	3.5 (2.1-5.0)
Allium sativum	21	75	3.2 (2.5-3.9)	28	32	2.8 (1.9-3.7)	18	43	3.5 (2.5-4.5)	29	50	2.8 (2.1-3.6)	10	25	4.2 (2.6-5.8)
Harpagophytum procumbens	22	75	3.2 (2.5-3.9)	18	39	3.4 (2.4-4.4)	26	36	3.0 (2.0-3.9)	40	40	2.3 (1.6-2.9)	5	35	5.9 (4.0-7.7)
Olea europaea	23	75	3.2 (2.5-3.9)	27	33	2.9 (1.9-3.8)	20	42	3.5 (2.4-4.4)	24	55	3.1 (2.3-3.9)	19	20	3.4 (1.9-4.8)
Glycyrrhiza glabra	24	74	3.1 (2.4-3.8)	26	33	2.9 (1.9-3.8)	22	41	3.4 (2.4-4.4)	25	54	3.1 (2.3-3.8)	18	20	3.4 (1.9-4.8)
Mentha piperita	25	72	3.1 (2.4-3.8)	20	36	3.2 (2.1-4.1)	27	36	3.0 (2.0-3.9)	27	53	3.0 (2.2-3.8)	22	19	3.2 (1.8-4.6)
Paullinia cupana	26	72	3.1 (2.4-3.8)	14	43	3.8 (2.7-4.8)	38	29	2.4 (1.5-3.2)	14	66	3.7 (2.9-4.6)	74	6	1.0 (0.2-1.8)
Malpighia glabra	27	71	3.0 (2.3-3.7)	15	41	3.6 (2.5-4.6)	37	30	2.5 (1.6-3.3)	18	61	3.5 (2.6-4.3)	51	10	1.7 (0.7-2.7)
Oenothera spec	28	70	3.0 (2.3-3.7)	41	23	2.0 (1.2-2.8)	14	47	3.9 (2.8-4.9)	21	59	3.3 (2.5-4.2)	47	11	1.9 (0.8-2.9)
Silybum marianum	29	69	2.9 (2.2-3.6)	25	34	3.0 (2.0-3.9)	30	35	2.9 (1.9-3.8)	32	46	2.6 (1.9-3.3)	12	23	3.9 (2.3-5.4)
Matricaria chamomilla	30	67	2.8 (2.2-3.5)	34	29	2.5 (1.6-3.4)	25	38	3.1 (2.1-4.1)	26	54	3.1 (2.3-3.8)	38	13	2.2 (1.0-3.3)
Citrus limon	31	66	2.8 (2.1-3.5)	37	24	2.1 (1.3-2.9)	19	42	3.5 (2.4-4.4)	30	48	2.7 (2.0-3.5)	25	18	3.0 (1.7-4.4)
Urtica dioica	32	64	2.7 (2.1-3.4)	31	30	2.6 (1.7-3.5)	34	34	2.8 (1.9-3.7)	28	51	2.9 (2.1-3.7)	37	13	2.2 (1.0-3.3)
Thymus vulgaris	33	63	2.7 (2.0-3.3)	36	28	2.5 (1.6-3.3)	31	35	2.9 (1.9-3.8)	33	44	2.5 (1.8-3.2)	24	19	3.2 (1.8-4.6)
Salvia officinalis	34	61	2.6 (2.0-3.2)	32	22	1.9 (1.1-2.7)	35	39	3.2 (2.2-4.2)	34	43	2.4 (1.7-3.1)	29	18	3.0 (1.7-4.4)
Cassia senna	35	60	2.5 (1.9-3.2)	43	29	2.5 (1.6-3.4)	24	31	2.6 (1.7-3.4)	37	43	2.4 (1.7-3.1)	28	17	2.9 (1.5-4.2)
Rosmarinus officinalis	36	60	2.5 (1.9-3.2)	38	24	2.1 (1.3-2.9)	28	36	3.0 (2.0-3.9)	39	41	2.3 (1.6-3.0)	23	19	3.2 (1.8-4.6)
Carum carvi	37	59	2.5 (1.9-3.1)	22	35	3.1 (2.1-4.0)	43	24	2.0 (1.2-2.7)	31	46	2.6 (1.9-3.3)	36	13	2.2 (1.0-3.3)
Hypericum perforatum	38	59	2.5 (1.9-3.1)	29	31	2.7 (1.8-3.6)	39	28	2.3 (1.5-3.1)	35	43	2.4 (1.7-3.1)	31	16	2.7 (1.4-4.0)
Lavandula angustifolia	39	57	2.4 (1.8-3.0)	40	23	2.0 (1.2-2.8)	32	34	2.8 (1.9-3.7)	36	43	2.4 (1.7-3.1)	35	14	2.4 (1.1-3.5)
Ribes nigrum	40	53	2.3 (1.7-2.8)	42	22	1.9 (1.1-2.7)	36	31	2.6 (1.7-3.4)	38	41	2.3 (1.6-3.0)	41	12	2.0 (0.9-3.1)

[a] Products ordered according to the consumer distribution of the overall top-40 used botanicals (unweighted ranking).

[b] Ranks show the shifts of the botanicals in the position of the overall 1-40 unweighted ranking when stratified by gender and age group.

Table 29. PlantLIBRA's PFS consumer survey – ranking of the overall top-40 botanicals' reported consumption when stratified by country.

Botanicals	Finland			Germany			Italy			Romania			Spain			United Kingdom		
	Rank[a]	n	% (95 % CI)	Rank[a]	n	% (95 % CI)	Rank[a]	n	% (95 % CI)	Rank[a]	n	% (95 % CI)	Rank[1]	n	% (95 % CI)	Rank[a]	n	% (95 % CI)
Ginkgo biloba		0	-	1	50	12.6 (9.3-15.8)	12	17	4.5 (2.4-6.6)	1	105	26.3 (21.9-30.6)	27	11	2.7 (1.1-4.3)	11	11	2.9 (1.2-4.6)
Oenothera biennis		0	-	22	15	3.8 (1.9-5.6)	174	1	0.3 (0.0-0.8)	164	1	0.3 (0.0-0.7)	20	13	3.2 (1.5-5.0)	1	164	43.2 (38.2-48.1)
Cynara scolymus	53	12	3.0 (1.3-4.7)	2	47	11.8 (8.6-15.0)	10	20	5.3 (3.0-7.6)	7	27	6.8 (4.3-9.2)	1	67	16.7 (13.0-20.3)		0	-
Panax ginseng	42	16	4.0 (2.1-5.9)	7	26	6.5 (4.1-9.0)	4	28	7.4 (4.8-10.1)	3	41	10.3 (7.3-13.2)	16	15	3.7 (1.9-5.6)	2	41	10.8 (7.7-13.9)
Aloe vera	172	1	0.3 (0.0-0.7)	25	12	3.0 (1.3-4.7)	1	44	11.6 (8.4-14.9)	2	47	11.8 (8.6-14.9)	37	8	2.0 (0.6-3.4)	4	33	8.7 (5.9-11.5)
Foeniculum vulgare ssp.	31	21	5.2 (3.1-7.4)	11	20	5.0 (2.9-7.2)	2	29	7.7 (5.0-10.4)	8	27	6.8 (4.3-9.2)	4	34	8.5 (5.7-11.2)	33	1	0.3 (0.0-0.8)
Valeriana officinalis	192	1	0.3 (0.0-0.7)	19	16	4.0 (2.1-6.0)	3	29	7.7 (5.0-10.4)	43	11	2.8 (1.2-4.4)	2	51	12.7 (9.4-15.9)	6	17	4.5 (2.4-6.6)
Glycine max	1	73	18.2 (14.4-22.0)	6	27	6.8 (4.3-9.3)	161	1	0.3 (0.0-0.8)		0	-	114	2	0.5 (0.0-1.2)		0	-
Melissa officinalis	14	39	9.7 (6.8-12.6)	12	20	5.0 (2.9-7.2)	7	25	6.6 (4.1-9.1)	74	5	1.3 (0.2-2.3)	18	14	3.5 (1.7-5.3)		0	-
Echinacea purpurea	3	55	13.7 (10.3-17.1)		0	-	59	5	1.3 (0.2-2.5)	13	24	6.0 (3.7-8.3)	70	4	1.0 (0.0-2.0)	7	14	3.7 (1.8-5.6)
Vaccinium myrtillus	23	30	7.5 (4.9-10.1)	30	12	3.0 (1.3-4.7)	5	28	7.4 (4.8-10.1)	15	20	5.0 (2.9-7.1)	43	8	2.0 (0.6-3.4)	26	2	0.5 (0.0-1.3)
Pimpinella anisum	16	36	9.0 (6.2-11.8)	28	12	3.0 (1.3-4.7)	38	8	2.1 (0.7-3.6)	21	15	3.8 (1.9-5.6)	11	18	4.5 (2.5-6.5)		0	-
Zingiber officinale	13	41	10.2 (7.3-13.2)	36	11	2.8 (1.2-4.4)	67	5	1.3 (0.2-2.5)	4	30	7.5 (4.9-10.1)	131	2	0.5 (0.0-1.2)		0	-
Camellia sinensis	28	23	5.7 (3.5-8.0)	16	16	4.0 (2.1-6.0)	22	12	3.2 (1.4-4.9)	47	10	2.5 (1.0-4.0)	6	26	6.5 (4.1-8.9)		0	-
Vitis vinifera	34	20	5.0 (2.9-7.1)	5	28	7.0 (4.5-9.6)	28	11	2.9 (1.2-4.6)	127	2	0.5 (0.0-1.2)	12	18	4.5 (2.5-6.5)	13	8	2.1 (0.7-3.6)
Taraxacum officinale	65	10	2.5 (1.0-4.0)	52	10	2.5 (1.0-4.1)	9	21	5.6 (3.2-7.9)	24	15	3.8 (1.9-5.6)	8	24	6.0 (3.7-8.3)		0	-
Echinacea angustifolia	2	55	13.7 (10.3-17.1)		0	-	48	6	1.6 (0.3-2.9)	117	2	0.5 (0.0-1.2)	31	10	2.5 (1.0-4.0)	15	6	1.6 (0.3-2.8)
Passiflora incarnata	75	8	2.0 (0.6-3.4)	62	7	1.8 (0.5-3.1)	6	26	6.9 (4.3-9.4)	65	7	1.8 (0.5-3.0)	5	30	7.5 (4.9-10.0)		0	-
Linum usitatissimum	24	28	7.0 (4.5-9.5)	27	12	3.0 (1.3-4.7)	95	3	0.8 (0.0-1.7)	14	24	6.0 (3.7-8.3)	73	4	1.0 (0.0-2.0)	16	6	1.6 (0.3-2.8)
Equisetum arvense	26	26	6.5 (4.1-8.9)	153	1	0.3 (0.0-0.7)	60	5	1.3 (0.2-2.5)	82	4	1.0 (0.0-2.0)	3	40	10.0 (7.0-12.9)		0	-
Allium sativum	27	25	6.2 (3.9-8.6)	92	3	0.8 (0.0-1.6)	69	4	1.1 (0.0-2.1)	64	7	1.8 (0.5-3.0)	7	24	6.0 (3.7-8.3)	10	12	3.2 (1.4-4.9)
Harpagophytum procumbens		0	-	9	21	5.3 (3.1-7.5)	20	13	3.4 (1.6-5.3)	55	9	2.3 (0.8-3.7)	40	8	2.0 (0.6-3.4)	5	24	6.3 (3.9-8.8)
Olea europaea	30	22	5.5 (3.3-7.7)	3	40	10.1 (7.1-13.0)		0	-	84	4	1.0 (0.0-2.0)	42	8	2.0 (0.6-3.4)	36	1	0.3 (0.0-0.8)
Glycyrrhiza glabra	47	14	3.5 (1.7-5.3)	18	16	4.0 (2.1-6.0)	17	14	3.7 (1.8-5.6)	10	26	6.5 (4.1-8.9)	71	4	1.0 (0.0-2.0)		0	-
Mentha piperita	4	47	11.7 (8.6-14.9)	24	14	3.5 (1.7-5.3)	78	4	1.1 (0.0-2.1)	75	5	1.3 (0.2-2.3)	119	2	0.5 (0.0-1.2)		0	-
Paullinia cupana	130	4	1.0 (0.0-2.0)	10	21	5.3 (3.1-7.5)	8	23	6.1 (3.7-8.5)	76	5	1.3 (0.2-2.3)	14	16	4.0 (2.1-5.9)	21	3	0.8 (0.0-1.7)
Malpighia glabra	12	41	10.2 (7.3-13.2)	21	15	3.8 (1.9-5.6)	18	14	3.7 (1.8-5.6)		0	-	169	1	0.3 (0.0-0.7)		0	-
Oenothera spec	10	43	10.7 (7.7-13.8)		0	-		0	-		0	-	10	20	5.0 (2.9-7.1)	14	7	1.8 (0.5-3.2)
Silybum marianum	190	1	0.3 (0.0-0.7)	35	11	2.8 (1.2-4.4)	15	15	4.0 (2.0-5.9)	23	15	3.8 (1.9-5.6)	19	14	3.5 (1.7-5.3)	9	13	3.4 (1.6-5.3)
Matricaria chamomilla	66	10	2.5 (1.0-4.0)	38	11	2.8 (1.2-4.4)	35	9	2.4 (0.8-3.9)	20	16	4.0 (2.1-5.9)	9	21	5.2 (3.1-7.4)		0	-
Citrus limon	7	43	10.7 (7.7-13.8)	112	2	0.5 (0.0-1.2)	29	10	2.7 (1.0-4.3)	146	1	0.3 (0.0-0.7)	30	10	2.5 (1.0-4.0)		0	-
Urtica dioica	9	43	10.7 (7.7-13.8)	53	10	2.5 (1.0-4.1)	133	2	0.5 (0.0-1.3)	89	4	1.0 (0.0-2.0)	66	5	1.2 (0.2-2.3)		0	-
Thymus vulgaris	6	47	11.7 (8.6-14.9)	177	1	0.3 (0.0-0.7)	66	5	1.3 (0.2-2.5)	87	4	1.0 (0.0-2.0)	53	6	1.5 (0.3-2.7)		0	-
Salvia officinalis	8	43	10.7 (7.7-13.8)	80	5	1.3 (0.2-2.4)	82	4	1.1 (0.0-2.1)	66	7	1.8 (0.5-3.0)	124	2	0.5 (0.0-1.2)		0	-
Cassia senna		0	-		0	-	11	19	5.0 (2.8-7.2)	11	25	6.3 (3.9-8.6)	22	12	3.0 (1.3-4.7)	17	4	1.1 (0.0-2.1)
Rosmarinus officinalis	64	10	2.5 (1.0-4.0)	34	11	2.8 (1.2-4.4)	129	2	0.5 (0.0-1.3)	12	25	6.3 (3.9-8.6)	25	12	3.0 (1.3-4.7)		0	-
Carum carvi		0	-	8	23	5.8 (3.5-8.1)	33	9	2.4 (0.8-3.9)	9	26	6.5 (4.1-8.9)	149	1	0.3 (0.0-0.7)		0	-
Hypericum perforatum		0	-	157	1	0.3 (0.0-0.7)	34	9	2.4 (0.8-3.9)	56	9	2.3 (0.8-3.7)	63	5	1.2 (0.2-2.3)	3	35	9.2 (6.3-12.1)
Lavandula angustifolia	17	34	8.5 (5.8-11.2)	161	1	0.3 (0.0-0.7)		0	-	60	8	2.0 (0.6-3.4)	32	10	2.5 (1.0-4.0)	19	4	1.1 (0.0-2.1)
Ribes nigrum	20	32	8.0 (5.3-10.6)	172	1	0.3 (0.0-0.7)	44	7	1.9 (0.5-3.2)	176	1	0.3 (0.0-0.7)	24	12	3.0 (1.3-4.7)		0	-

[a] Ranks show the shifts of the botanicals in the position of the overall 1-40 unweighted ranking when stratified by country.

2.3.4 Discussion

The present paper reports the findings from a European multi-country survey of PFS consumers: the PlantLIBRA PFS consumer survey. Data on the usage of PFS at the European level are limited, confined in the main to commercial market data (EAS 2007) as opposed to consumer survey data, as evidenced in the recent review by Bishop and Lewith (2010), where only 13% of population based consumption studies were in Europe. The EFSA has recognised the lack of data in the sector and has published a number of reports addressing related issues (EFSA 2009; EFSA 2012).

To our knowledge this is the first survey of consumers of PFS undertaken in Europe. In total 2359 consumers of PFS were recruited in this cross-sectional retrospective survey. Across all countries prevalence of usage is estimated at 18.8%. Vargas-Murga and colleagues (2011) highlighted that comparable data at European level is difficult to identify when reviewing prevalence data from a selected number of European studies, evaluating PFS or CAM usage, with values ranging from 0.8% to 70%. All studies were based on nationally representative samples but the definition of use of supplements varied widely, in some cases being self-defined by the participant and not distinguishing between PFS and HMP. The use of dietary supplements in a European population was measured in the European Prospective Investigation into Cancer and Nutrition (EPIC) study (Skeie et al. 2009). Usage was measured by completion of a standardised 24-hour dietary recall and included all dietary supplements that met the EU Directive 2002/46/EC. Results indicated significant differences in overall dietary supplement use between countries with herbs/plant-based supplements representing 8-17% of the products used across the ten countries.

The prevalence rate reported here can be compared to rates from surveys conducted in the United States, where data on usage of dietary supplements, including herbal supplements, is collected more routinely. It is similar to the rate reported in the 2002 and 2007 National Health Interview Surveys (NHIS), 18.9% and 17.9% respectively (Wu *et al.* 2011); higher than the rates of both the Eisenberg's survey (Eisenberg *et al.* 1998) and the Slone survey (Kauffman *et al.* 2002), with 14% and 12.1% respectively; and lower than the 2002 Health and Diet Survey (42%) (Timbo *et al.* 2006) or the 1999 Kaiser Permanent Medical Care Program of Northern California (KPMCP), with a prevalence of 28.3% (Schaffer *et al*. 2003). These differences in prevalence across studies may in part be due to the distinct selected population samples, survey methodologies (i.e. sampling methods, data collection techniques) or definitions of usage, as well as possible variations in health beliefs and health behaviour of the different populations of study (Vargas-Murga *et al.* 2011; Dwyer *et al.* 2013).

Survey respondents were recruited to set quotas for both age and gender to reflect characteristics previously reported for dietary supplement users. Age and gender are significant determinants of the consumption of dietary supplements in general and in botanical products in particular. Previous studies on the use of dietary supplements or other herbal-related use show a higher consumption among women as compared to men (Menniti-Ippolito *et al.* 2002; NCHS 2009; Schaffer *et al.* 2003; Messerer *et al.* 2001; Nilson *et al.* 2001; Nielsen *et al.* 2005; Thomas *et al.* 2001) and a higher consumption among older adults as compared to younger adults (Schaffer *et al.* 2003; Foote *et al.* 2003; Radimer *et al.* 2004; Kelly *et al.* 2005; Bailey *et al.* 2013).

Other characteristics of dietary supplements users that have been reported previously in the literature include having higher educational attainment and socioeconomic status (Schaffer *et al.* 2003; Rock 2007; Block *et al.* 2007), being less likely to smoke (Harrison *et al.* 2004; Bailey *et al.* 2013; Touvier *et al.* 2009), being more physically active (Harrison *et al.* 2004; Foote *et al.* 2003; Bailey *et al.* 2013). Bailey *et al.* (2013) also reported a moderate alcohol consumption (1 drink per day) among dietary supplement users as compared to nonusers. In contrast, a study by Rovira et al. in a southern European population found no differences in lifestyle factors such as physical activity, smoking, and alcohol consumption between dietary supplement users and non-users (Rovira *et al.* 2013). Our survey population consists exclusively of PFS consumers, but their responses to a series of questions on health-related lifestyle factors reflect some of the characteristics mentioned above. The majority of PFS consumers perceived their health status to be “very good or good”, reflecting results reported in a number of studies on dietary supplement users (Bailey *et al.* 2013) and CAM and dietary supplement users (Schaffer *et al.* 2003), where the answer “very good or excellent” has been reported for self-reported health status.

The survey results indicate that most consumers reported using one PFS product in the preceding 12 months, with 12% using two products and 4% using more than two. Individual country data show that Finnish consumers use more than one product and PFS with more than one botanical component, and the opposite is observed in the United Kingdom, where about 90% of the consumers use only one PFS and the products contain mostly only one botanical. In the United States, recent studies have reported that about half of the adults report using one or more dietary supplements

(Bailey *et al.* 2013; Picciano *et al.* 2007). One of these studies also found that over half of dietary supplement consumers used a single-botanical product and one third used one multi-botanical product (Bailey *et al.* 2013). Similar results were found in our survey across all countries i.e. smaller numbers of consumers reported using two or more single-botanical products (4.4%) and two or more single- and multi-botanical products (11.9%).

A wide variety of botanicals (491) is used in PFS consumed by the respondents in this survey. Overall raw data show that the most frequently (n>100) used botanicals in descending order are *Ginkgo biloba* (ginkgo), *Oenothera biennis* (evening primrose), *Cynara scolymus* (artichoke), *Panax ginseng* (ginseng), *Aloe vera, Foeniculum vulgare* (fennel), *Valeriana officinalis* (valeriana), *Glycine max* (soybean), *Melissa officinalis* (lemon balm), *Echinacea purpurea* (echinacea) *and Vaccinium myrtillus* (blueberry). These results reflect some commercial data which reported that ginkgo followed by echinacea, garlic and ginseng were the four most commercially important botanicals in the combined markets of seventeen EC Member States. In this data, echinacea and ginkgo were part of the composition of products registered as medicines (EAS 2007; Vargas-Murga *et al.* 2011), which were excluded from our survey. Similarly, the US Food and Drug Administration 2002 Health and Diet Survey, also a 12-month retrospective study, reported the same four herbs/botanicals/or other nonvitamin-nonmineral dietary supplements being the most used by its adult population – although in the following order: echinacea, garlic, ginkgo and ginseng (the latter including tea) (Timbo *et al.* 2006). Schaffer et al. also reported echinacea as the most consumed botanical in the Californian 1999 KPMCP survey, followed by ginkgo (Schaffer *et al.* 2003). Differences between countries are more evident; the top list of botanicals contained in PFS for each single country complies little with the ranking of the overall data. As mentioned earlier, data were not weighted by country population size because of the study methodology which included very similar country-sample sizes of PFS consumers only, therefore caution is needed when drawing conclusions from these results at the overall 6-country level. Overall data merely describes the collected pooled data from all 6 countries. However, if the overall ranking data were to be weighted by the population size -for example the 1-5 ranking data-, the positions of the botanicals would have been only slightly altered, with *Oenothera biennis* (evening primrose) being the most consumed one, followed by *Cynara scolymus* (artichoke) *Ginkgo biloba* (ginkgo), *Panax ginseng* (ginseng) and *Aloe vera* (aloe).

The results of the survey highlight clear differences between countries in terms of the botanicals used by consumers as PFS. This may reflect the fact that the current legal and regulatory framework for botanicals has a major influence on the nature of the local PFS markets. The EU Directive 2002/46/EC does not provide a clear definition of what is encompassed by the term ‘other substance with a nutritional or physiological effect’, although it is generally accepted that botanicals and their extracts fall into this category. Current legislation varies across Europe, with significant differences in the botanical species permitted in PFS. These issues were highlighted in a recent review of the regulations applicable to PFS in the EU by Silano et al. (Silano *et al.* 2011). They provide examples of the different national approaches for the use of selected botanicals in food supplements in the EU Member States.

To illustrate the above complexity, in Germany, food supplements are regulated by the German Regulation on Food Supplements (NemV 2004) and the German Law on Food and Feed (LFGB 2006). Positive lists are available for minerals and vitamins. Food supplements have to be registered with the Federal Office of Consumer Protection and Food Safety (BVL 2010). The BVL maintains a list of plants which are either classified as a food or a medicinal product, and which is neither considered complete nor legally binding (BVL 2010). Data on the intake of PFS in Germany is limited and, despite food supplement intake being recorded in recent health and nutrition surveys (Finger *et al.* 2013; BFR 2013; Max Rubner Institut 2008), no specific data was published on PFS intake. The results from the PlantLIBRA consumer survey do not include *Valeriana officinalis* in the German top list of botanicals used in PFS, whereas 1852 medicinal products containing Valerian exist on the market (LFGB 2006). The absence of *Valeriana officinalis* in the German list of botanicals can be explained by its dominant presence as a HMP in the German market.

The results of this survey represent some of the first data on the usage of PFS at European level, thus addressing the existing deficit of such data by collecting retrospective data directly from consumers in six European countries. The benefits of the data collection instrument used in this study included that it was relatively straightforward to administer, did not alter habitual usage patterns and allowed the classification of individuals into categories of usage. However, the results must be considered in the light of their limitations. The sample population comprises exclusively of PFS consumers, recruited to meet very specific inclusion criteria and hence no comparisons can be made with the general population. Future studies should seek to compare users and non-users of PFS.

Further limitations relate to the retrospective nature of the data being collected. In many cases respondents needed to rely on memory to report usage of products in the preceding 12 months. Where products are available for inspection at data collection, there is a need for careful recording of product details to ensure accurate coding. The lack of a comprehensive product database containing reliable ingredient information meant a bespoke database needed to be created. Future studies should seek to collect prospective data. Prospective dietary intake surveys offer an ideal opportunity to collect data on supplement use in conjunction with data on food and beverages. Care needs to be taken to collect sufficiently detailed information about ingredients and amounts consumed. For example, in the US, the Alternative Health/CAM supplement of the National Health Interview Survey (NHIS) is part of an annual, nationally representative survey of US adults. It contains data on adults' use of 10 herbs most commonly taken to treat a specific health condition in the preceding 12 months (Bardia *et al.* 2007); the survey has a separate section on dietary supplements and distinguishes "natural herbs" from vitamins and minerals. The authors would like to encourage researchers to implement future surveys/studies which are necessary to overcome the bottlenecks in PFS risk and benefit assessments at the European level.

2.4 – Chapter 4:

BMI overweight and obesity in relation to plant food supplements usage in six European countries: results from the PlantLIBRA PFS Consumer Survey 2011-2012

2.4.1 Introduction

Obesity is a global epidemic (Prentice 2006; Caballero 2007). Many individuals are seeking strategies for reducing their body weight and fat levels. These strategies may include surgery in severe/morbid obesity (Colquitt *et al.* 2014), and both lifestyle and pharmacotherapy interventions in overweight and non-morbid obesity. The latter two mainly include; hypocaloric and hyperproteic diets, whose mechanisms of action may involve, among others: decreased energy intake and appetite suppression (Denke 2001); increased physical activity and thus increased energy output (Dwyer *et al.* 2005); weight-loss drugs such as the lipase inhibitor Orlistat (NIH MedlinePlus-Orlistat) and the appetite suppressant Sibutramine (NIH MedlinePlus-Sibutramine); and weight-loss food supplements, including plant food supplements (PFS), such as appetite suppressants or those increasing resting metabolism (Dwyer *et al.* 2005).

An emerging problem is that the general population seems to prefer plant-based slimming aids to conventional dietary and physical activity (Licata *et al*. 2013). Plant food supplements that claim to induce weight loss are marketed worldwide and are readily available over the Internet (De Carvalho *et al.* 2011; Ancuceanu *et al.* 2013; Ozdemir *et al.* 2013). This increased usage has coincided with a resurgence of interest in nutritional therapy and complementary and alternative medicine (CAM) therapies (Ritchie 2007). Plant food supplements and dietary therapies for weight loss are among the most common CAM modalities (Barnes *et al.* 2004). Many reasons are behind this preference: they are promoted as requiring less effort than other behavioural changes (i.e. diet and exercise); are heavily advertised with claims of effectiveness; are easily available without a prescription (Pillitteri *et al*. 2008); are commonly marketed on the Internet (Jordan & Haywood 2007); are believed to be “natural” and “harmless”; and are beyond the control of drug regulatory agencies (Licata *et al.* 2013). Moreover, there is no perceived need for professional assistance with these strategies and individuals who cannot afford to visit a physician often view PFS as a more accessible solution (Heber 2003). For many other individuals, these strategies represent alternatives to failed attempts at losing weight using more conventional approaches; these consumers are often discouraged by previous experiences and are likely to combine strategies or use these supplements at doses higher than recommended (Heber 2003; Pilliteri *et al.* 2008).

The fact that weight-loss PFS do not follow rigorous safety controls before entering the market is causing a serious public health problem evidenced by the worldwide accumulating studies of hepatotoxicity from their use (Duque *et al*. 2007; Herrera & Bruguera 2008; Chitturi & Farrell 2008; Licata *et al*. 2013; Navarro & Seeff 2013). According to Navarro & Seeff, in the United States, products used for bodybuilding and weight loss are the most commonly implicated to cause liver injury (Navarro & Seeff 2013). Nevertheless, there is an ongoing debate about the validity of the diagnosis of herbal hepatotoxicity or herb induced liver injury (HILI) in past studies, because major methodological pitfalls for the evaluation of causality have been identified, and therefore, the diagnosis of HILI currently represents a clinical and regulatory challenge (Teschke *et al.* 2013).

Actions are already been taken by governments to tackle this problem in countries with the highest consumption prevalence of weight-loss supplements, such as the United States (US) or Japan (Euromonitor International 2014 a). For instance, in the US, the National Institutes of Health (NIH) committed substantial funding to dietary supplement research in the financial years 2009-2010-2011. The objective was to expand the scientific knowledge base on the efficacy and safety of dietary supplements, with botanicals being the dietary supplement ingredients receiving the most funding (Garcia-Cazarin *et al.* 2014). In Europe, the assessment of the efficacy and safety of food supplements including botanicals is also being addressed, also urged by the increasing usage of these products: in 2010, the EU project PlantLIBRA (acronym of “PLANT Food Supplements: Levels of Intake, Benefit and Risk Assessment”) was launched, a multidisciplinary 3-year project co-financed in the context of the 7th EU Framework Program (see section 1.2.2).

The study of weight-loss food supplements in the last decade has been very active and the literature is extensive, focusing on different interdisciplinary aspects, such as their sales and marketing (Sharpe *et al.* 2006; Nutrition Business Journal 2014; Euromonitor International 2014 b), their effectiveness/efficacy (Egger *et al.* 1999; de Lira-García *et al.* 2008), and their safety/adverse effects (Yellapu *et al.* 2011). There are many systematic reviews summarizing the available scientific evidence in the literature (Allison *et al.* 2001; Saper *et al.* 2004; Pittler & Ernst 2004; Dwyer *et al.* 2005; Pilliteri *et al.* 2008; Onakpoya *et al.* 2011; Manore 2012). Worldwide literature that focuses particularly on weight-loss PFS and their individual ingredients is also numerous and has increased in the last few years. Researchers have focused on summarizing in literature systematic reviews of randomized controlled clinical trials (RCTs) the effectiveness evidence of these products (Heber 2003; Pittler *et al.* 2005; Hasani-Ranjbar *et al.* 2009; Park *et al.* 2012; Astell *et al.* 2013) or of individual botanical ingredients (such as *Phaseolus vulgaris* RCTs, reviewed by Onakpoya *et al.* (2011); some have actually conducted RCTs for assessing individidual botanicals effectiveness/efficacy for weight loss (e.g. Keithley *et al.* 2013; Hackman *et al.* 2006) and adverse effects (e.g. hepatotoxicity studies mentioned above; Pittler *et al.* 2005); and others have evaluated the availability of weight-loss products (including herbals) in the local markets (Sharpe *et al.* 2006; Dickel *et al.* 2006).

Nevertheless, very few surveys have been conducted on the use of these products and there is little information on who is using them and the botanicals included in weight-loss PFS reported by actual users. A number of multi-country, national, regional or local surveillance surveys have asked about use of supplements (Eisenberg *et al.* 1998; Kauffman *et al.* 2002; Radimer *et al.* 2004; Timbo *et al.* 2006; Skeie *et al.* 2009) and some of them have included CAM and herbal supplements sections (NHIS 2002, 2007 and 2012 CAM sections; Nilsson *et al.* 2001; Thomas *et al.* 2001; Schaffer *et al.* 2003; Bardia *et al.* 2007; Wu *et al.* 2011). In spite of this, the focus of these papers in not specifically for weight-loss herbal supplements, but rather any supplement use, such as vitamin and mineral use, or CAM use or the use of the most commonly taken herbs to treat a specific health condition (Bardia *et al* 2007). At the European level, the recent “PlantLIBRA PFS Consumer Survey 2011-2012” is the first source of data available that has allowed to conduct an analysis on weight-loss PFS (Garcia-Alvarez *et al.* 2013) in 6 European countries.

Few recent studies on botanical use and weight-loss have been identified. The larger-scale ones were conducted in the US. The most relevant one used data from the 2002 National Physical Activity and Weight Loss Survey (final n=9,403); it assessed prevalence and duration of non-prescription weight-loss supplement use, associated weight-control behaviours, discussion of use with a health care professional, and specific ingredient use (Blanck *et al.* 2008). Another US study used data on CAM use from the 2002 National Health Interview Survey (NHIS) Alternative Medicine Supplement (n=31,044) and compared the use of CAM overall, within the previous year, between four categories of adult BMI (Bertisch *et al.* 2008). The third and smaller US study used data from a 2005-2006 nationally representative survey (n=3,500 adults), and assessed dietary supplement use for weight loss and perceptions about safety, efficacy and regulatory oversight of these products (Pillitteri *et al.* 2008). Outside the US, a 2009 survey in the Polish city of Szczecin evaluated the range of weight-loss programmes and behaviours associated with the use of slimming supplements (appetite inhibitors or fat burning and thermogenesis enhancers), observed among 300 female university students (Sadowska & Szuber 2011). The last study was a cross-sectional population-based survey conducted in 2,732 adults living in the Brazilian city of Pelotas that aimed to determine the prevalence of weight-loss practices and use of substances for weight-loss during the 12 months preceding the interview (Machado *et al.* 2012).

Because weight-loss PFS usage data are very scarce, with almost no data on the actual botanical ingredients consumed by BMI status, the objectives of this research chapter are two: 1) to identify the PFS botanical ingredients consumed for "body weight reasons" and by "dieters for overweight/obesity"; and 2) to explore the relationship between the consumption of these botanical ingredients and the self-reported BMI of their consumers. Data from the six-EU-country "PlantLIBRA PFS Consumer Survey 2011-2012" have been used.

2.4.2 Materials and methods

Survey sample

This study has been carried out within the PlantLIBRA project (FP7-EC funded project nº245199). Data on PFS usage were collected in Finland, Germany, Italy, Romania, Spain and the United Kingdom, in a cross-sectional, retrospective survey of 2359 PFS consumers using a bespoke frequency-of-PFS-usage questionnaire (see Annex III). For further details about the methodology of the PlantLIBRA PFS Consumer Survey (sampling, questionnaires, data collection, databases, etc) and the concepts and definitions used, please refer to Chapter 3's "Material and methods" section.

Study samples

Analyses were performed on 3 subsamples of the PlantLIBRA PFS Consumer Survey: 1) PFS consumers who responded to take the products for "body weight reasons" (n=240), i.e. who answered option 6 of the question *"For what reason(s)/condition(s) did you take this product? Mark all that apply" (*of 20 possible anwers); 2) PFS consumers who responded to be "dieting for overweight/obesity" (n=112), i.e. who answered option 5 of the question *"Please indicate the special diet that you follow. Mark all that apply" (*of 16 possible answers); and 3) PFS consumers who belonged to the cross-tabulation of subsamples 1 and 2 (n=67), i.e. who responded to take the product for “body weight reasons” while “dieting for overweight/obesity”.

Variables

A number of variables were created and/or recoded to facilitate reporting and analysis, including: 1)“body weight reason”, with two categories: “Did not respond body weight” (i.e. PFS products not taken for the reason “body weight”) and “Responded body weight” (i.e. PFS products taken for the reason “body weight”); 2)“dieting”, with two categories: “not dieting for ove/obe” (i.e. PFS consumers who were not dieting for overweight/obesity) and “dieting for ove/obe” (i.e. PFS consumers who were dieting for overweight/obesity); 3)“BMI”, which was calculated from self-reported weight and height, and for which WHO criteria (WHO 2013) were used to categorise individuals as “underweight-and-normal weight” ($BMI<25kg/m^2$) and “overweight-and-obese” ($BMI\geq25kg/m^2$); 4)“education level”, defined as low, medium, and high; 5)“employment status”, defined as “currently employed” and “other groups”; 6)“physical activity”, calculated using the short version of the IPAQ (Craig *et al.* 2003) and defined as low, moderate or high; 7) “food frequency”, defined as grams/day of fruit, vegetables, bakery and pastries, soft drinks and fast food.

Statistical analyses

The statistical package SPSS for Windows v. 18 (IBM Corporation, Somers, NY, USA) was used for data analysis.

The subsamples of “body weight reasons” respondents and non-respondents was described in terms of the above variables/characteristics, using both χ^2 and t tests for categorical and mean comparisons ($p<0.05$ for significance). Frequencies and percentages of the variables “responded body weight reason” and “dieting for ove/obe” were stratified by country. Absolute frequencies, percentages and 95% confidence intervals of the top 20 botanical ingredients contained in products taken by “respondents and non-respondents of body weight reason” and by “overweight/obesity dieters and non-dieters” were calculated, as well as those of the top 10 botanical ingredients contained in products taken by consumers who “responded body weight" and who were simultaneously "dieting for overweight/obesity", i.e. these individuals would be the “pure weight-watchers”. The frequency of a botanical is the number of times that a botanical was found in the composition of the total number of PFS consumed pooled from all consumers, regardless of the consumers who took them and regardless of whether the botanical came from a single- or multi-ingredient product, i.e. no “weight” was given to the particular botanical within the product.

Chi-squared test was used to test the relationship between the 5 most consumed botanicals and self-reported BMI in subsamples 1 and 2, by comparing BMI proportions of consumers vs. non-consumers of these botanicals (p<0.05 for significance). Comparisons were made using a) the “body weight reasons” subsample and the “dieters for overweight/obesity” subsample in which the top 5 consumed botanicals were actually identified (n=240 and n=112 respectively), and b) the total survey PFS consumer sample (N=2359), in order to increase the power of the test. Finally, absolute frequencies of the top botanical ingredient contained in the consumed PFS were stratified by country.

As mentioned in chapter 3, it is important to bear in mind that when reporting the results, the unit of analysis varies depending on the variables used, i.e. for certain variables the unit is an individual respondent, for others it may change to the PFS product level, or to the level of the botanical ingredient contained in the product. Furthermore, data were not weighted by the population size because of the study methodology selected, whereby all country samples were very similar in size and included only PFS consumers. All results presented in the tables represent the analysis of raw data.

2.4.3 Results

Characteristics of PFS users for reasons of body weight and of PFS users for other reasons

Table 30 shows the characteristics of the overall survey sample, and also of the sample stratified by whether or not the consumer responded to take the PFS for “body weight reasons”. A prevalence of 10.2% users of PFS for “body weight reasons” was observed, whose profile showed a higher proportion of: 1) women, 2) women aged 18-59 rather than 60+, 3) individuals from Spain, 4) individuals with a BMI≥25, 5) individuals with a medium education level, 6) currently employed individuals, 7) individuals who are not on a diet for overweight/obesity (72.1% vs. 27.9%), 8) individuals with a low level of physical activity, 9) never smokers -followed by current smokers, and of 10) individuals that consume alcohol less than once a day. The differences are only significant in cases 1), 3), 4), 7-10). As for food frequency, those who did not respond to take PFS for “body weight reasons” had a higher mean consumption of pastries/cakes and soft-drinks per day as compared to respondents of “body weight reasons”.

Table 30. Sample characteristics, overall and by response to the question on reasons to take the PFS product (did not respond "body weight", responded “body weight”).

Characteristics	All categories	Total (N=2359)		Did not respond Body Weight (n=2119, 89.8%)		Responded Body Weight (n=240, 10.2%)		
		n	%	n	%	n	%	χ^2 *p*-value*
Gender	Males	1141	48.4	1055	49.8	86	35.8	0.000
	Females	1218	51.6	1064	50.2	154	64.2	
Age (years)	18-59	1764	74.8	1578	74.5	186	77.5	0.306
	>60	595	25.2	541	25.5	54	22.5	
Country	Finland	401	17.0	364	17.2	37	15.4	0.000
	Germany	398	16.9	362	17.1	36	15.0	
	Italy	378	16.0	345	16.3	33	13.8	
	Romania	400	17.0	375	17.7	25	10.4	
	Spain	402	17.0	305	14.4	97	40.4	
	United Kingdom	380	16.1	368	17.4	12	5.0	
BMI (kg/m^2)	<25	1185	50.2	1089	51.4	96	40.0	0.001
	>25	1174	49.8	1030	48.6	144	60.0	
Education	Low	249	10.6	223	10.5	26	10.8	0.109
	Medium	1549	65.7	1379	65.1	170	70.8	
	High	561	23.8	517	24.4	44	18.3	
Employment	Currently employed	1357	57.5	1210	57.1	147	61.3	0.218
	Other groups	1002	42.5	909	42.9	93	38.7	
Dieting	Not dieting for ove/obe[a]	2247	95.2	2074	97.9	173	72.1	0.000
	Dieting for ove/obe[a]	112	4.8	45	2.1	67	27.9	
Physical activity	Low	1214	51.5	1067	50.4	147	61.3	0.006
	Moderate	1033	43.8	950	44.8	83	34.6	
	High	112	4.7	102	4.8	10	4.2	
Smoking habit	Never smoker	1100	46.6	1005	47.4	95	39.6	0.032
	Former smoker	544	23.1	488	23.0	56	23.3	
	Current smoker	715	30.3	626	29.5	89	37.1	
Alcohol consumption	0-<1 time/day	1398	82.5	1251	82.0	147	87.5	0.074
	>1 time/day	296	17.5	275	18.0	21	12.5	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	***t*-test *p*-value***
Food frequency (g/day)	Fruit	1.34	1.04	1.35	1.06	1.25	0.94	ns
	Vegetable	0.95	0.91	0.94	0.91	1.01	0.93	ns
	Bakery and pastries	0.49	0.96	0.51	0.99	0.3	0.62	0.002
	Soft drinks	1.07	1.79	1.11	1.83	0.79	1.33	0.011
	Fast food	0.09	0.26	0.09	0.27	0.08	0.14	ns

a. Ove/obe: overweight/obesity; *p<0.05 for significance.

Country distribution of products taken for body weight reasons and consumers dieting for overweight/obesity

Figure 23 shows that of the total 2874 PFS products consumed, 252 (8.8%) products were reported to be consumed for “body weight reasons” (by 240 PFS consumers), Spain being the country with the most PFS taken for this reason (21.5%).

Figure 23. PFS products taken for "body weight reasons" (%), by country

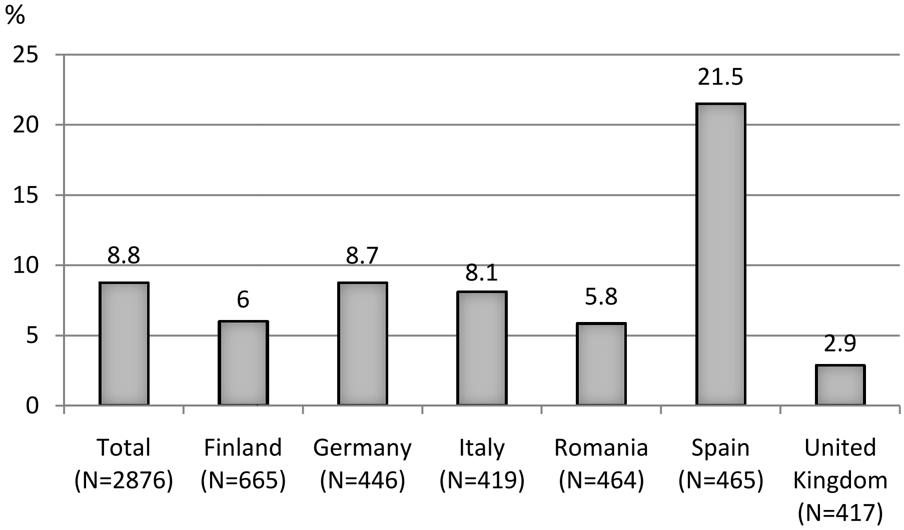
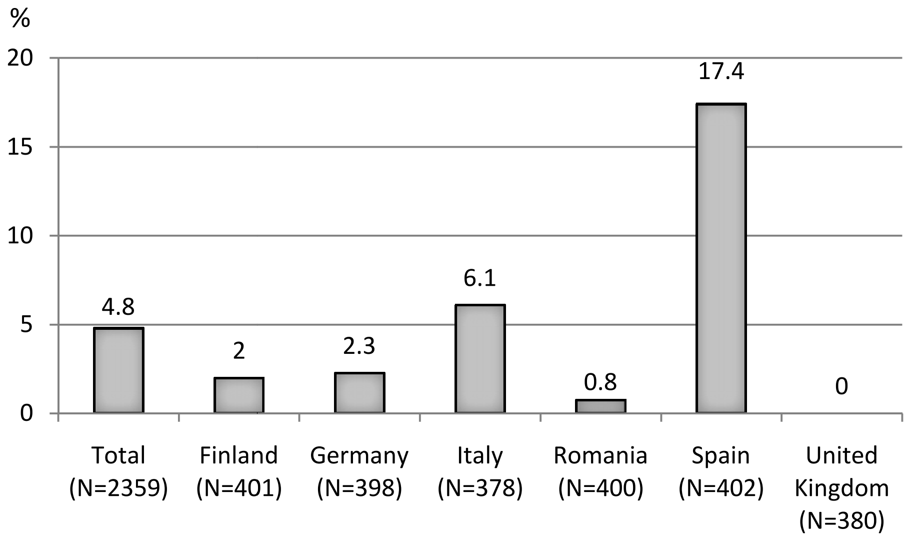


Figure 24 shows that of the total 2359 PFS consumers of the survey, 112 (4.8%) reported to be “dieting for overweight/obesity”, Spain being the country with most dieters.

Figure 24. PFS Consumers "dieting for overweight/obesity" (%), by country



Most consumed botanicals by respondents of "body weight reasons", "dieters for overweight/obesity" and "dieters for overweight/obesity responding body weight"

Tables 31 and 32 show the top 20 botanicals consumed by each of the two groups of analysis, and Table 33 shows the top 10 botanicals consumed by a third group that cross-tabulates both groups of analysis i.e. the "respondents of body weight reason" who are also "dieting for overweight/obesity". Artichoke is the most consumed botanical by consumers of all three groups (contained in the 6.1%, the 7% and the 8.6% of the PFS consumed by respondents of body weight reason, by dieters for overweight/obesity and by the cross-tabulation of the two, respectively), and it is followed by green tea in the first group and by fennel in the other two groups.

Table 31. Top 20 botanicals contained in the PFS taken by "consumers who did not respond 'body weight'" and by those who "did respond 'body weight'" when asked for the reasons to take the product[a].

PFS taken by those who did not respond "body weight"[b]			PFS taken by those who responded "body weight"[c]		
Botanicals consumed	**n PFS**	**% (IC 95%)**	**Botanicals consumed**	**n PFS**	**% (IC 95%)**
Ginkgo biloba (ginkgo)	191	3.05 (2.62-3.47)	*Cynara scolymus* (artichoke)	72	6.08 (4.72-7.44)
Oenothera biennis (evening primrose)	184	2.94 (2.52-3.35)	*Camellia sinensis* (green tea)	37	3.12 (2.13-4.11)
Panax ginseng (ginseng)	160	2.55 (2.16-2.94)	*Foeniculum vulgare* (fennel)	34	2.87 (1.92-3.82)
Aloe vera (aloe)	132	2.11 (1.75-2.46)	*Vitis vinifera* (grapevine)	23	1.94 (1.16-2.73)
Valeriana officinalis (valerian)	123	1.96 (1.62-2.31)	*Ananas comosus* (pineapple)	21	1.77 (1.02-2.52)
Cynara scolymus (artichoke)	101	1.61 (1.30-1.92)	*Taraxacum officinale* (dandelion)	21	1.77 (1.02-2.52)
Echinacea purpurea (echinacea)	100	1.60 (1.29-1.91)	*Pimpinella anisum* (aniseed)	19	1.60 (0.89-2.32)
Foeniculum vulgare (fennel)	98	1.56 (1.26-1.87)	*Rosmarinus officinalis* (rosemary)	19	1.60 (0.89-2.32)
Melissa officinalis (lemon balm)	95	1.52 (1.21-1.82)	*Linum usitatissimum* (flax)	17	1.43 (0.76-2.11)
Glycine max (soy bean)	91	1.45 (1.16-1.75)	*Vaccinium myrtillus* (bilberry)	17	1.43 (0.76-2.11)
Vaccinium myrtillus (bilberry)	83	1.32 (1.04-1.61)	*Citrus limon* (lemon)	15	1.27 (0.63-1.90)
Echinacea angustifolia (echinacea)	77	1.23 (0.96-1.50)	*Raphanus sativus* (radish)	15	1.27 (0.63-1.90)
Harpagophytum p. (devil's claw)	75	1.20 (0.93-1.47)	*Urtica dioica* (common nettle)	15	1.27 (0.63-1.90)
Passiflora incarnata (passionflower)	74	1.18 (0.91-1.45)	*Zingiber officinale* (ginger)	15	1.27 (0.63-1.90)
Zingiber officinale (ginger)	74	1.18 (0.91-1.45)	*Matricaria chamomilla* (Hungarian camomile)	15	1.27 (0.63-1.90)
Allium sativum (garlic)	71	1.13 (0.87-1.39)	*Malus pumila* (apple)	14	1.18 (0.57-1.80)
Pimpinella anisum (aniseed)	70	1.12 (0.86-1.38)	*Aloe vera* (aloe)	13	1.10 (0.50-1.69)
Glycyrrhiza glabra (licorice)	67	1.07 (0.81-1.32)	*Equisetum arvense* (horsetail)	13	1.10 (0.50-1.69)
Oenothera spec (evening primrose)	65	1.04 (0.79-1.29)	*Fucus vesiculosus* (kelp)	13	1.10 (0.50-1.69)
Mentha piperita (peppermint)	64	1.02 (0.77-1.27)	*Olea europaea* (olive tree)	13	1.10 (0.50-1.69)

[a] Question asked: *For what reason(s)/condition(s) did you take this product? (mark all that apply)* - twenty possible options were available. [b] Neither of the options chosen included "body weight". [c] At least one of the options chosen included "body weight".

Table 32. Top 20 botanicals contained in the PFS taken by consumers who are not and those who are "dieting for overweight/obesity"[a].

Did not respond "Dieting for ove/obe"[b]			Responded "Dieting for ove/obe"[c]		
Botanicals consumed	**n PFS**	**% (IC 95%)**	**Botanicals consumed**	**n PFS**	**% (IC 95%)**
Oenothera biennis (Evening primrose)	193	2.77 (2.36-3.17)	*Cynara scolymus* (artichoke)	34	7.04 (6.41-7.67)
Ginkgo biloba (ginkgo)	191	2.74 (2.34-3.14)	*Foeniculum vulgare* (fennel)	17	3.52 (2.28-3.20)
Panax ginseng (ginseng)	166	2.38 (2.00-2.76)	*Taraxacum officinale* (dandelion)	14	2.90 (1.97-2.80)
Aloe vera (aloe)	143	2.05 (1.70-2.40)	*Ananas comosus* (pineapple)	13	2.69 (1.65-2.45)
Cynara scolymus (artichoke)	139	1.99 (1.65-2.34)	*Matricaria chamomilla* (Hungarian camomile)	11	2.28 (1.62-2.36)
Valeriana officinalis (valerian)	120	1.72 (1.40-2.04)	*Camellia sinensis* (green tea)	10	2.07 (1.37-2.07)
Foeniculum vulgare (fennel)	115	1.65 (1.33-1.96)	*Rosmarinus officinalis* (rosemary)	10	2.07 (1.30-2.00)
Echinacea purpurea (echinacea)	102	1.46 (1.17-1.76)	*Fucus vesiculosus* (kelp)	9	1.86 (1.13-1.80)
Melissa officinalis (lemon balm)	102	1.46 (1.17-1.76)	*Paullinia cupana* (guarana)	9	1.86 (1.13-1.80)
Glycine max (soy bean)	98	1.41 (1.11-1.70)	*Vitis vinifera* (grapevine)	9	1.86 (1.07-1.74)
Vaccinium myrtillus (bilberry)	95	1.36 (1.08-1.65)	*Raphanus sativus* (radish)	8	1.66 (1.05-1.68)
Zingiber officinale (ginger)	87	1.25 (0.97-1.52)	*Sambucus nigra* (elder)	8	1.66 (0.93-1.56)
Pimpinella anisum (aniseed)	82	1.18 (0.91-1.44)	*Carica papaya* (papaya)	7	1.45 (0.88-1.47)
Echinacea angustifolia (Echinacea)	79	1.13 (0.87-1.40)	*Citrus limon* (lemon)	7	1.45 (0.84-1.43)
Vitis vinifera (grapevine)	78	1.12 (0.86-1.38)	*Pimpinella anisum* (aniseed)	7	1.45 (0.82-1.41)
Camellia sinensis (green tea)	77	1.10 (0.85-1.36)	*Silybum marianum* (milk thistle)	7	1.45 (0.81-1.40)
Linum usitatissimum (flax)	75	1.08 (0.82-1.33)	*Smilax officinalis* (sarsaparilla)	7	1.45 (0.78-1.37)
Passiflora incarnate (passionflower)	75	1.08 (0.82-1.33)	*Asparagus officinalis* (asparagus)	6	1.24 (0.80-1.35)
Harpagophytum p. (devil's claw)	74	1.06 (0.81-1.32)	*Equisetum spec.* (horsetail & scouring rush)	6	1.24 (0.79-1.34)
Allium sativum (garlic)	73	1.05 (0.80-1.30)	*Cassia senna* (senna)	5	1.04 (0.80-1.30)

[a] Question asked: *Are you following any special diet(s) which would cause you to avoid certain foods? (mark all that apply)* – sixteen possible options were available. [b] Neither of the options chosen included "overweight/obesity". [c] At least one of the options chosen included "overweight/obesity".

Table 33. Top 10 botanicals contained in the PFS taken by consumers who "responded body weight" when asked for the reasons to take the product[a] and who were simultaneously "dieting for overweight/obesity"[b].

"Responded body weight" and "Dieting for ove/obe"		
Botanicals consumed	**n PFS**	**% (IC 95%)**
Cynara scolymus (artichoke)	27	8.57 (5.48-11.66)
Foeniculum vulgare (fennel)	13	4.13 (1.93-6.32)
Ananas comosus (pineapple)	11	3.49 (1.46-5.52)
Matricaria chamomilla (Hungarian camomile)	10	3.17 (1.24-5.11)
Taraxacum officinale (dandelion)	9	2.86 (1.02-4.70)
Fucus vesiculosus (kelp)	8	2.54 (0.80-4.28)
Raphanus sativus (radish)	8	2.54 (0.80-4.28)
Rosmarinus officinalis (rosemary)	8	2.54 (0.80-4.28)
Camellia sinensis (green tea)	7	2.22 (0.59-3.85)
Carica papaya (papaya)	7	2.22 (0.59-3.85)

[a] At least one of the options chosen included "body weight". [b] At least one of the options chosen included "overweight/obesity".

BMI differences between consumers and non-consumers of the 5 most used botanicals

Table 34 shows BMI differences between consumers and non-consumers of the top 5 botanicals consumed for "body weight reasons", when using a) the respondents of "body weight reasons" subsample or b) the entire survey sample. In case "a", no significant differences are observed. However in case "b", a greater proportion of consumers of PFS containing artichoke (58.4%) and green tea (63.2%) have a BMI$\geq$25 kg/m^2 as compared to non-consumers (49.1% and 49.7% respectively) (p=0.019 and p=0.043 respectively).

Table 34. BMI distribution differences between consumers and non-consumers of the top 5 botanicals consumed by those who responded "body weight reasons" for PFS use, when using a) the "body weight" subsample and b) the entire survey sample.

		BMI				
		<25 kg/m^2		≥25 kg/m^2		
Top 5 consumed botanicals for "body weight"	**Consumption group**	**n**	**%**	**n**	**%**	**χ^2 *p*-value***
a) When using only the subsample of consumers responding "body weight" (N=240)						
Cynara scolymus (artichoke)	Consumers	24	33.3	48	66.7	0.168
	Non-consumers	72	42.9	96	57.1	
Foeniculum vulgare ssp. (fennel)	Consumers	15	40.5	22	59.5	0.942
	Non-consumers	81	39.9	122	60.1	
Camellia sinensis (green tea)	Consumers	17	50	17	50	0.199
	Non-consumers	79	38.3	127	61.7	
Vitis vinifera (grapevine)	Consumers	6	26.1	17	73.9	0.152
	Non-consumers	90	41.5	127	58.5	
Ananas comosus (pineapple)	Consumers	10	47.6	11	52.4	0.456
	Non-consumers	86	39.3	133	60.7	
b) When using the entire sample of consumers (N=2359)						
Cynara scolymus (artichoke)	Consumers	72	41.6	101	58.4	**0.019**
	Non-consumers	1113	50.9	1073	49.1	
Foeniculum vulgare ssp. (fennel)	Consumers	71	53.8	61	46.2	0.401
	Non-consumers	1114	50	1113	50	
Camellia sinensis (green tea)	Consumers	32	36.7	55	63.2	**0.043**
	Non-consumers	1142	50.3	1130	49.7	
Vitis vinifera (grapevine)	Consumers	43	49.4	44	50.6	0.878
	Non-consumers	1142	50.3	1130	49.7	
Ananas comosus (pineapple)	Consumers	21	60	14	40	0.244
	Non-consumers	1164	50.1	1160	49.9	

*p<0.05 for significance.

Table 35 shows BMI differences between consumers and non-consumers of the top 5 botanicals consumed by "dieters for overweight/obesity", when using a) the "dieters" subsample or b) the entire survey sample. In case "a", the proportion of BMI≥25 is lower among consumers of pineapple-containing PFS (38.5%) as compared to non-consumers (81.8%) (*p*=0.000). In case "b", the proportion of BMI≥25 is greater among consumers of artichoke-containing PFS (58.4%) than among non-consumers (49.1%) (*p*=0.019).

Table 35. BMI distribution differences between consumers and non-consumers of the top 5 botanicals consumed by "dieters for overweight/obesity", when using a) the "dieters for overweight/obesity" subsample and b) the entire survey sample.

Top 5 consumed botanicals by "dieters for overweight/obesity"	Consumption group	BMI <25 kg/m² n	BMI <25 kg/m² %	BMI ≥25 kg/m² n	BMI ≥25 kg/m² %	χ^2 *p*-value*
a) Using only the subsample of consumers responding to be "dieting for overweight/obesity" (N=112)						
Cynara scolymus (artichoke)	Consumers	9	26.5	25	73.5	0.590
	Non-consumers	17	21.8	61	78.2	
Foeniculum vulgare ssp. (fennel)	Consumers	5	29.4	12	70.6	0.511
	Non-consumers	21	22.1	74	77.9	
Taraxacum officinale (dandelion)	Consumers	3	21.4	11	78.6	0.866
	Non-consumers	23	23.5	75	76.5	
Ananas comosus (pineapple)	Consumers	8	61.5	5	38.5	**0.000**
	Non-consumers	18	18.2	81	81.8	
Matricaria chamomilla (chamomile)	Consumers	1	9.1	10	90.9	0.243
	Non-consumers	25	24.8	76	75.2	
b) Using the entire sample of consumers (N=2359)						
Cynara scolymus (artichoke)	Consumers	72	41.6	101	58.4	**0.019**
	Non-consumers	1113	50.9	1073	49.1	
Foeniculum vulgare ssp. (fennel)	Consumers	71	53.8	61	46.2	0.401
	Non-consumers	1114	50	1113	50	
Taraxacum officinale (dandelion)	Consumers	39	48.8	41	51.3	0.787
	Non-consumers	1146	50.3	1133	49.7	
Ananas comosus (pineapple)	Consumers	21	60	14	40	0.244
	Non-consumers	1164	50.1	1160	49.9	
Matricaria chamomilla (chamomile)	Consumers	32	47.8	35	52.2	0.681
	Non-consumers	1153	50.3	1139	49.7	

*p<0.05 for significance.

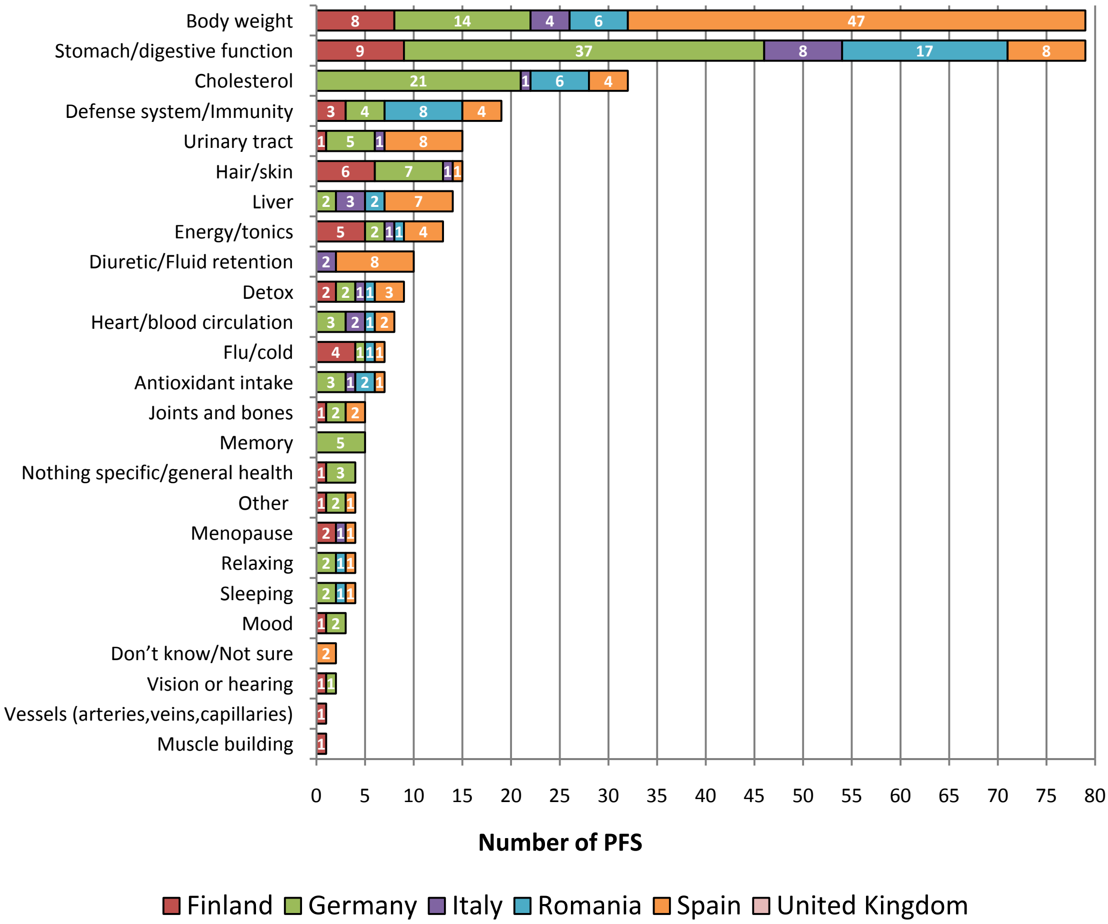
BMI differences among consumers and non-consumers of botanicals taken by the third group could not be analysed due to the small size of some cells. Only BMI differences among consumer and non-consumers of artichoke were tested and they were not significant (p=0.826). Country comparisons could not either be performed due to size restrictions.

Country distribution of the number of artichoke-containing PFS used for body weight and other health reasons

Figure 25 shows the number of artichoke-containing PFS used for body weight and other health reasons in each country. The three first reasons for taking artichoke-containing products were "body weight", "stomach/digestive function" and "cholesterol". Spain was the country with more PFS consumed for body weight reasons (47/79), followed by Germany (with 14/79). However, the same total number of products were used for stomach/digestive function, being most used in Germany (37/79), followed by

Romania (17/79). Cholesterol is the third health reason reported by users of artichoke-containing products, being most used in Germany (21/32).

Figure 25. Number of *Cynara scolymus* (artichoke)-containing PFS used for body weight and other health reasons, by country.



2.4.4 Discussion

The study presented in this chapter provides an overview of the botanical ingredients contained in PFS that were used by consumers of these products in six European countries that participated in the PlantLIBRA PFS Consumer Survey 2011. The botanical ingredients are identified in the subsample of PFS consumers that a) use these products for body weight reasons, b) are overweight/obesity dieters, and c) in consumers who take PFS for body weight reasons and are also dieting. The study also explores the relationship between the use/non-use of the top weight-loss PFS botanical ingredients and self-reported BMI of survey participants.

The PFS consumers who take these products for reasons of body weight are predominantly women, living in Spain, overweigh and obese (with BMI≥25), non-dieters for overweight/obesity, with a low physical activity level, never smokers, low alcohol consumers, and less frequent consumers of bakery, pastries and soft-drinks. This profile suggests that individuals who use PFS for body weight reasons are health conscious and may turn to these products under the belief that this is a safe/innocuous and effort-free strategy to lose or maintain weight, a belief that other researchers have confirmed (Allison *et al.* 2001; Pitller & Ernst 2004). Other studies have reported dietary-supplement consumer profiles with similar gender results to those of the present study, but with disparate results for the other factors (Harrison *et al.* 2004; Pillitteri *et al.* 2008; Blanck *et al.* 2008; Machado *et al.* 2012).

The present study has also found that of the total 2874 PFS products consumed, 252 (8.8%) products were reported to be consumed for body weight reasons in the previous 12 months by 240 PFS consumers of 2359, i.e. a prevalence of weight-loss PFS users of 10.2%. Harrison *et al.* reported higher rates in Northwest England, with the percentage of those taking at least one herbal supplement being 12.8% (1,987/15,465), although it referred to general use and not to weight-loss use (Harrison *et al.* 2004). Blanck *et al.* reported an estimated lower 8.7% of past year use of "non-prescription weight-loss supplements" (including dietary supplements and natural or herbal weight loss aids not prescribed by a doctor); they used data from the 2002 US National Physical Activity and Weight Loss Survey (n=9,403), an observational nationwide cross-sectional telephone survey conducted by the University of South Carolina Prevention Research Center. However, their percentage referred to an overall weight-loss supplements without specifying the contribution by herbal/botanical ones (Blanck *et al.* 2007). Moreover, in their study using data on CAM use from the 2002 US National Health Interview Survey (NHIS) Alternative Medicine Supplement (n=31,044), Bertisch *et al.* reported higher prevalence of "natural herbs use" (between approximately 17% and just over 20% depending on BMI category, with normal weight individuals showing the highest rate); but this study focused on CAM therapies use and did not specify the format in which the natural herbs were used (Bertisch *et al.* 2008). Another survey on US adults, a computer-assisted telephone interview conducted by the Center for Survey Research and Analysis at the University of Connecticut in 2005-2006, reported a much higher prevalence of use: of the adults who made a serious weight-loss attempt (n=1,444), 33.9% reported ever using a “dietary supplement for weight loss” (including “over-the-counter appetite suppressants, herbal products, or weight-loss supplements”, although not separating them) (Pillitteri *et al.* 2008). Lastly, in their recent study (n=2,732) in the city of Pelotas, Brazil, Machado *et al.* reported that the prevalence of use of “substances for weight-loss” was 12.8%; however, these substances included teas, dietary supplements (unspecified) and medicines (Machado *et al.* 2012). Therefore, comparison of results and extrapolation of conclusions among the few publications evaluating the use of weight-loss supplements at the population level are limited. It is hard to reconcile all their different prevalence rates, since none of the studies really coincided in using a similar terminology (concepts and definitions ranged between “natural herbs”, “non-prescription weight loss supplements”, or “substances for weight-loss”), or similar objectives, study designs, sample sizes, and data collection methodology. The present study is the first study to evaluate the use of weight-loss supplements in already consumers of PFS in six European countries, having used the same terminology and methods to allow straight country comparison.

Some studies have evaluated the use of weight-loss practices in populations (Kruger *et al.* 2004; Weiss *et al.* 2006), and dieting and exercise seem to be the most effective and safe ones (Nicklas *et al.* 2012). The present study has focused on dieting and has estimated the prevalence of dieting for overweight/obesity: 4.8% of 2359 PFS consumers of six European. Similar rates were reported in one study (Blanck *et al.* 2008). Its authors observed that among those currently trying to stay about the same weight, 4.4% were users of weight-loss dietary supplements during the past year; however, among “persons currently trying to lose weight”, 16.1% reported past-year use of these products (around a four-fold higher rate). In addition, Pillitteri *et al.* observed much higher rates, reporting that of the adults who made a serious weight-loss attempt (n=1,444), 33.9% had ever used a dietary supplement for weight loss (Pillitteri *et al.* 2008); their findings are similar to those of Machado *et al.*, reporting a prevalence of use of substances for weight-loss of those who tried to lose weight of 48.4% (Machado *et al.* 2012). Again, comparison with other results is awkward because of the different study designs, terms and methods used to obtain the data. For instance, Blanck *et al.*’s study did not separate herbal/plant food supplements from other types of supplement, and our study did not specify if the respondents were trying to lose or to maintain weight (only asked if currently on a diet and what type of diet); in Machado *et al.* (2012), teas were the most frequently used substances for weight-loss, which were excluded in our study.

The present study is one of the very few studies evaluating the simultaneous use of several weight-loss strategies, such as dieting and PFS use, because we evaluate dieting in PFS consumers. We hypothesized that our "pure weight-watching" consumers (those taking the products in an attempt to lose/maintain weight) would be those responding "body weight reasons" and also responding to be "dieting for overweight/obesity" (n=67, i.e. 27.9% of the "body weight respondents"). The literature has recognized that on hypocaloric diets, the addition of dietary supplements may help dieters to achieve nutrient adequacy and maintain electrolyte balance while avoiding the risk of excessive nutrient intakes (Dwyer et al. 2005). However, a recent study concluded that taking weight-loss supplements may create illusion of protection against weight gain and thereby loosen subsequent dietary self-control, increasing food intake and susceptibility to overeating (Chang & Chiou 2014).

This is the first study in a sample of PFS consumers from six EU countries that has identified the botanicals that were contained as ingredients in more products used by "respondents of body weight reason", by "overweight/obesity dieters" and by the "body weight respondents who are simultaneously on a diet for overweight/obesity". Artichoke was the botanical that appeared as ingredient in the greatest number of consumed PFS in all three groups (6.1%, 7% and 8.5% respectively); green tea (3.1%) and fennel (2.9%) were second and third in the first group; fennel (3.5%) and dandelion (2.9%) were second and third in the second group; and fennel (4.1%) and pineapple (3.5%) were second and third in the third group. To our knowledge, only one recent US study has reported the actual botanicals contained in used weight-loss supplements and the prevalence of users (Blanck *et al.* 2008). They reported totally different botanicals consumed among past-year supplement users: almost three fourths (73.8%) used a product classified as a stimulant, more than half (55.0%) took a product containing ephedra, one in 15 used a product containing bitter orange, and one in 10 took hydroxycitric acid (*Garcinia cambogia*); other active herbal ingredients, such as conjugated linoleic acid and yerba mate, were in very few of the products reported in the study and, therefore, did not yield stable prevalence estimates (Blanck *et al.* 2008). The latest systematic review of RCTs assessing the effectiveness as appetite suppressants of botanical ingredients in weight-loss products found that many botanical species including crude extracts and isolated compounds from plants have been shown to provide potentially promising therapeutic effects, becoming an alternative strategy for obesity treatment (Astell *et al.* 2013). According to this review, plant based supplements marketed as natural appetite suppressants and weight loss aids include: *Camellia sinensis, Caralluma fimbriata, Citrus aurantium, Coleus* *forskohlii, Garcinia cambogia* and *Phaseolus vulgaris.* Out of the six, only *Caralluma fimbriata* extract has received the Generally Recognized As Safe (GRASS) (Dutt *et al.* 2012) status for use as a nutraceutical for obesity treatment, with positive clinical trials providing sufficient evidence that it is capable of curbing central obesity; however, further studies are needed to determine its efficacy as an appetite suppressant (Astell *et al.* 2013). The others need to be further investigated to define the magnitude of the effects, optimal dosage, mechanisms of action, long term safety, and potential side effects.

Out of the top three botanical ingredients contained in the PFS consumed in our survey (in each subsample), only green tea is included for assessment of weight-loss effectiveness in all identified recent effectiveness RCTs systematic reviews (Hursel *et al*. 2009; Park *et al.* 2011; Onakpoya *et al.* 2011; Hasani-Ranjbar *et al.* 2013; Astell *et al.* 2013), non-systematic literature reviews (Manore 2012) and in an audit of retail outlets to assess the availability of weight-loss supplements in the city of Columbia-SC-US (Sharpe *et al.* 2006). Artichoke, pineapple and fennel are not included for effectiveness assessment in any systematic or non-systematic review of the literature. However, they are mentioned in a publication that reviewed the literature prior to 2003 and presented Spanish data on reported products/ingredients retailed/purchased for weight loss; this information and data were gathered by the Spanish Society of Endocrinology and Nutrition through their Information Centre on Obesity (data on green tea was also presented) (de Villar *et al.* 2003). Artichoke alone is also included in a publication on a survey in the Brasilian city of Porto Alegre, in which 14 herbalists (herb sellers) were interviewed about popular use of plants with weight loss purposes, aiming to establish a correlation between popular use and biological properties (Dickel *et al.* 2006).

Regarding green tea, conclusions vary across publications: different authors have reported the evidence to be “inexistent” (de Villar *et al.* 2003), “uncertain” (Saper *et al.* 2004), “only modest” (Sharpe *et al.* 2006), or that green tea is “efficacious for weight reduction and maintenance because it stimulates fat oxidation and energy expenditure” (Hursel *et al.* 2009; Astell *et al.* 2013), or that it “may complement a health lifestyle to produce small weight losses or prevent weight gain over time” (Manore 2012), or that “the poor methodological quality of its studies did not allow to draw definitive conclusions” (Onakpoya *et al.* 2011; Park *et al.* 2012), or that evidence of effectiveness was “acceptable” (Hasani-Ranjbar *et al.* 2013), or “not effective in promoting weight loss through appetite suppression” (Astell *et al.* 2013). Therefore, scientific evidence for weight-loss effectiveness of green tea remains inconsistent and inconclusive, and further research is needed.

As for artichoke (the most consumed botanical in Spain, as shown in chapter 3's ranking of botanicals), the identified publications concluded that scientific evidence for weight-loss effectiveness is "untested/inexistent" (de Villar *et al.* 2003) and "insufficient to guarantee the efficacy and safety for treating obesity but could be useful to treat some of its comorbidities (i.e. hyperlipidemia)". In their review, de Villar *et al.* reported the following information about artichoke (de Villar *et al.* 2003): "it is a substance frequently used in slimming products; it is used in cases of biliary dyskinesia, gallstones, cholelithiasis, anorexia, dyspepsia, and as a diuretic; other indications of traditional use include arteriosclerosis and hyperlipidemia. Its potential effectiveness as a slimming substance was revealed during a clinical trial with 60 hyperlipidemic patients -after 50 days a 20% decrease in cholesterol levels and a weight loss of 5 kg were observed (Montini *et al.* 1975)". Moreover, the Spanish Centre for Phytotheray Research (Centro de Investigación sobre Fitoterapia - INFITO) has stated in their publication "Plantas medicinales para el tratamiento del sobrepeso" ("Medicinal plants for the treatment of overweight") that "sometimes it is convenient to include in slimming preparations plants that have an activity on the liver and gallbladder, they can generally improve the digestive and liver functions or to help reduce some of the risk factors associated obesity, such as hyperlipidemia. Artichoke can be used as adjuvant in the treatment to reduce body weight" (INFITO 2009).

With regard to pineapple, we only found one publication that included it as an ingredient of popularly consumed weight loss products, again in Spain. In this publication, authors outlined the main therapeutic indications/recommendations of pineapple at that time (2003), distinguishing the "true" ones (burns, skin lesions) from the "traditional-use" ones (dyspepsia, arthralgia, arthritis, stomatitis, cellulitis, exocrine pancreatic insufficiency and obesity; including a comment of "mild diuretic effect"), and concluded that scientific evidence for weight-loss effectiveness is "untested/non-existent" (de Villar *et al.* 2003). However, a recent publication might have relevant findings (Dave *et al.* 2012), in which authors concluded that, at the cell level, the phytotherapeutic protein stem bromelain (obtained from pineapple), together with all-trans retinoic-acid, may be a potent modulator of obesity by repressing the PPARc-regulated adipogenesis pathway at all stages and by augmenting TNFa-induced lipolysis and apoptosis in mature adipocytes. Despite this publication results and the active advertisement on the Internet, scientific evidence on weight loss effectiveness of pineapple is currently considered non-existent.

Finally, no publication was found including fennel as an ingredient of weight loss supplements despite the extensive and recent scientific literature describing its uses and properties (Rahimi & Ardekani 2013; Badgujar *et al.* 2014). However, as for pineapple, advertisements promoting fennel-containing products as a slimming aid on the Internet are numerous, which might suggest an explanation to the high prevalence of consumption by our dieters and body weight reason respondents. Another hypothesis might involve the fact that some of the properties attributed to fennel are “improves digestion”, “prevent bloating” and “flavor corrector” i.e. it might be acompaning other substances in weight-loss multi-ingredient supplements to improve digestion, neutralize intestinal gas formation and soften their flavor.

Our results are consistent with the recommendations of use of artichoke as adjuvant of weight loss treatments at least in Spain, the country with the highest prevalence of “body weight reason respondents” (21.5%) and “dieters” (17.4%) and where artichoke-containing products were most used for body weight reasons (47/79 PFS). These results are also in line with some reports in the literature, such as the ‘‘White Book of herbal shops and medicinal plants’’, a report about the situation of the Spanish herbal shop sector (Fundación Salud y Naturaleza 2007), in which the authors report that the top-selling products are food supplements (29%) followed by weight control products (28%). We explored other reasons of use of artichoke in the six survey countries, what has allowed us to observe that there is also agreement with the recommendations of use for stomach/digestive function and cholesterol (highest in Germany). We cannot know at this stage the reasons behind the different use prevalence rates of the same botanical across the six countries. They might respond to different regulatory restrictions between the countries, market consumption trends, marketting strategies related to traditional/cultural believes, etc. Further research involving a long-term study design, a larger sample size, market, regulatory, and anthropological data, as well as, stratification by gender, season of the year, among other explanatory variables -which was not allowed in our study due to the small size of the samples, would be needed to elucidate possible reasons behind.

Our results show significant BMI differences between consumers and non-consumers of artichoke (first most consumed botanical of respondents of “body weight reasons” and of “dieters for overweight/obesity”) and green tea (third most consumed botanical of respondents of "body weight reasons") when the entire survey sample (n=2359) was used to increase the power of the comparison: more consumers than non-consumers of each botanical were overweight/obese (BMI$\geq$25 kg/m^2). However, only among dieters, very significant BMI differences were observed for pineapple, with consumers having higher rates of normal weight (BMI<25 kg/m^2) than non-consumers. We do not know why this is happening, and we cannot infer causality from these results due to the cross-sectional nature of the survey. Bertisch *et al.*, who analysed the relationship between obesity and the use of CAM (including natural herbs), reported that adults with obesity had similar prevalence of use of natural herbs compared to normal-weight individuals, and after adjustment by some factors they were generally less likely to use most individual CAM modalities (Bertisch *et al.* 2008). Nevertheless, Bertisch et al.'s study and our study are not comparable because they evaluated the overall use of natural herbs as a CAM modality in the general population, instead of the use of botanical ingredients among PFS consumers. To our knowledge, our study is the first study that has tested BMI differences between consumers and non-consumers of particular botanicals contained in PFS.

The present study has several limitations. The survey was not designed to assess weight loss. All data were self-reported, allowing the possibility of misreporting - although with regards to the products, the interviewers verified the packaging of approximately 50% of them. In addition, the survey did not collect composition/label data (mostly unavailable), therefore, dosages of botanicals could not be calculated for BMI/dosage analyses. The definition of the product "plant food supplement" is so specific that results can really only be compared with results from other studies with this definition. The cross-sectional nature of the survey does not allow inference of causality. The design of the survey (only including PFS consumers and quota sampling) does not allow either the weighting of the data, the extrapolation of results to the general population or the comparison with general population studies. Finally, the survey had a small sample size that allowed limited stratification and no regression analyses for assessing the association between BMI and botanical ingredients consumption vs. non-consumption and identifying significant predictors.

This study has some unique strengths. It is the first study that –using the same methodology- has identified the most consumed botanicals by PFS consumers from six European countries who responded to take these products for reasons of "body weight" or who were "dieting for overweight/obesity". In addition, the "PFS product" was very clearly defined and differenciated from other herbal products, which will allow direct comparison with future studies on weight loss and PFS consumption that might be conducted. Moreover, this study has corroborated the denounced fact that consumers are using botanicals for weight loss whose effectiveness has not been proven or is inconclusive, and yet, they are being largely marketed on the Internet (Dwyer *et al.* 2005; Astell *et al.* 2013). Finally, the study has identified some of the many possibilities for future research to try and explain the differences in weight-loss botanical/product use across national markets within the EU. It would be important to have data on the exact amounts of the botanicals contained in the products consumed in order to differentiate the "essential body-weight-control" botanical from the "complementary" botanical within the multi-ingredient weight-loss product.

In conclusion, the literature on the use of PFS for weight loss is very scarce and at the moment, results are not really comparable. The research community is rather active in conducting RCTs and systematic reviews on the RCTs effectiveness of weight loss botanicals, paying special attention to their safety and adverse effects, which is unquestionably important and necessary. However, it is also very important to keep on gathering data on the weight-loss botanicals that the large population is consuming, why and how they are been consumed, and if there are any differences between consumers and non-consumers of these botanicals in terms of their body weight indicators (BMI, WC etc) and other factors. Although limited by a small sample size, our study represents a first attempt (and hopefully not the last) to reach these objectives in six EU countries. The authors would like to encourage the research community to carry out further studies on this topic, studies that are long-term, with large sample sizes from the general population (i.e. PFS consumers and non-consumers, ideally as part of regional/national health/nutrition/CAM-use surveys), and that allow to collect label data on ingredients amounts and dosages. This additional information would help elucidate the many unknowns about the marketing, consumption and effectiveness of PFS specifically used as a strategy for body weight control.

3. Conclusions and original contributions

3. CONCLUSIONS AND ORIGINAL CONTRIBUTIONS

The results of the research carried out in this thesis have significant implications for public health. It has long been established that excess body weight is an increasing public health problem, affecting more and more societies of all sorts, including affluent, in transition and emerging ones. It is also well known that this public health problem is influenced by many factors. Some of these factors are addressed in the four research chapters of this thesis.

As regards chapter 1, it has evaluated the trends of general and central overweight and obesity prevalence rates in the adult population of Catalonia, Spain, and the influence of socio-economic variables on these prevalence trends. Ten-year trends indicated that Catalan males were getting bigger overall (BMI) and around the waistline (WC), while Catalan females only had bigger waistlines (WC). BMI male obesity prevalence had overtaken that of females. WC obesity continued to be more prevalent among females than males, especially those from lower SES groups (occupation and education levels). In spite of the mentioned limitations, findings contribute to the evidence needed to guide public health policy makers in the design and implementation of preventive campaigns against the increasing trends of overweight and obesity, paying special attention to males and low SEL and education level groups, and small population of residence size (for male overweight and female obesity). Moreover, analyses also revealed that WC obesity continued to be more prevalent among females than males, especially those from lower SES groups (occupation and education levels). The literature has shown that changes in WC accompany changes in cardiovascular risk factors; WC also predicts morbidity and mortality and is strongly associated with metabolic abnormalities. Therefore, chapter 1‘s findings for the Catalan adult female population would encourage urgent weight management actions to improve this collective’s health and to prevent abdominal adiposity co-morbidities, with special focus on the lower SES groups. This study was published in the journal *Public Health Nutrition* 2007 (impact factor (IF) in 2008: 2.123) (see Annex IVa), and presented as a poster at the VIII SENC Congress, Valencia, 22-25 October 2008.

In addition, based on the fact that tobacco smoking can be used by individuals as a weight control strategy, chapter 2 has assessed, again in the adult Catalan population of the two ENCAT surveys, ten-year prevalence trends in observed general/central fatness patterns among subjects of different smoking habits It has also examined the association between smoking and both general/central fatness after adjusting for possible confounders. And finally, it has contributed to the understanding of how these relationships change with temporal trends in the prevalence of both obesity and smoking. Although causality cannot be established, results suggest a positive association between heavy smoking and central fatness among men; the very small number of women who reported to be heavy smokers may be limiting the ability to examine associations between current heavy smoking and central obesity and compare them with those observed in men. Nevertheless, no association between former smoking and general/central fatness was observed in the latest survey, and these findings strengthen arguments for promoting smoking cessation to reduce morbidity and mortality associated with both smoking and obesity. This research chapter contributes to the global pool of evidence about this topic, because this has never been studied before in the Catalan population. The manuscript has been submitted to a scientific journal (see Annex IVb).

It is important to mention that one of the most interesting aspects about working on chapters 1 and 2 has been the actual analysis of the two ENCAT surveys. The fact that these surveys are representive, identical and separated by ten years allows a dynamic view of the evolving health and habits of the Catalan population; this should help in health policy decision-making. Working with the ENCATs has represented the added bonus to this thesis for making a good contribution.

Chapters 3 and 4 respectively explore the consumption of PFS in six EU countries and the relationship between their consumption and the reported BMI of their consumers. The motivation of the research in chapter 4 is that a wide range of PFS is popularly used for body weight control/loss. The two studies presented in these two chapters were carried out using data from the PlantLIBRA EU project's PFS Consumer Survey 2011-2012, which is the first survey of PFS consumers conducted at European level.

In particular, Chapter 3 encloses the first results on the consumption of PFS in relation to (among many other collected variables) the type of product consumed, the frequency of its consumption, and the botanical ingredients most frequently contained in these consumed products. Obtaining and handling all this information was a rather complex task, and conducting the survey in 6 EU countries simultaneously added in even more challenges. The survey is one of the main outcomes of the PlantLIBRA EU project and has represented a contribution to scientific research in this sector at the European level. Thanks to this project and survey, nowadays there are available data directly obtained from consumers in six EU countries that can be used in the future to carry out various types of research. In addition, a new methodology has been proposed and tested, which can be used and improved by future researchers of the topic for generating additional data. Thus, for example, incorporating measures of the intake of botanicals in national dietary surveys would provide much-needed data for comprehensive risk and benefit assessments at the European level towards the EC policy-making and regulation of the sector. The first results of the survey were disseminated through numerous presentations before the project ended and through a publication in the journal *PLoS One* 2014 (IF in 2013/2014: 3.53) (see Annex IVc).

Finally, the PLantLIBRA PFS Consumer Survey data gave the opportunity to further exploit data to try and address the topic "excess body weight in relation to the consumption of PFS". Chapter 4 provides an overview of the PFS botanical ingredients consumed for "body weight reasons" and by "overweight/obesity dieters" in six European countries; it also explores the relationship between the consumption of these botanical ingredients and the self-reported BMI of their consumers. Although limited by a small sample size and a lack of "composition data" (actual amounts of the botanical ingredients), our study represents a first attempt (and hopefully not the last) to explore the relationship "BMI-PFS consumption" in six EU countries. Findings should encourage the research community to carry out further studies on this topic. Future studies should as much as possible be long-term, with large sample sizes from the general population (i.e. PFS consumers and non-consumers, ideally as part of regional/national health/nutrition/CAM-use surveys), and that allow collecting label data on ingredients amounts and dosages. This additional information would help elucidate the many unknowns about the marketing, consumption and effectiveness of PFS specifically used as a strategy for body weight control (in some countries like Spain rather prevalently). It is important to keep on gathering data on the weight-loss botanicals that populations are consuming, why and how they are being consumed, and if there are any differences between consumers and non-consumers of these botanicals in terms of their body weight indicators (BMI, WC etc) and other aspects of health. This research was presented as a poster at the *III World Congress of Public Health Nutrition*, Las Palmas de Gran Canaria, 9-12 November 2014 (see Annex IVd). The article is pending submission to one of the following journals (IF in 2013-2014): 1) *Phytomedicine* (2.877) or 2) *Plant Foods For Human Nutrition* (2.416) or 3) *Phytotherapy Research* (2.397) or 4) *Planta Medica* (2.339).

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4. Annexes

ANNEX I: WHO 2008 Expert Consultation on waist circumference and waist-hip ratio.

WHO 2008 Expert Consultation on waist circumference and waist-hip ratio.

Recommendations (WHO 2008, page 24)

Ideally, the characteristics associated with the most useful analyses for one or more uses of waist circumference or waist–hip ratio would be that:

- the data are representative of all population groups (with respect to age, sex, social class and concurrent diseases) in countries from all regions;
- data collected include anthropometric measures (of both central adiposity and BMI) and at least three risk factors (e.g. blood pressure, blood glucose and cholesterol);
- standardized methods were used for measurement of waist circumference and other anthropometric indicators;
- measured weight and height were available and were not self-reported data;
- the dataset include information on characteristics such as age, sex and demographics;
- sufficient longitudinal data from appropriate populations be available, with high quality follow-up of disease status along the time course, to permit confirmation of key conclusions about cut-off points derived using cross-sectional data.

Given the data available, the consultation felt that the steps presented below (which are not in any specific order) could be taken to arrive at appropriate WHO recommendations in this critical area:

- Determine whether multiple sets of cut-off points will be needed (e.g. by sex, body size or health-status characteristics of the population). This could be accomplished by evaluating similarities or differences in the associations of waist circumference or waist–hip ratio with various health outcomes, across populations or population subgroups. The approach would compare populations that differ in distributions of waist circumference and waist–hip ratio, or in disease profiles. Type 2 diabetes should be considered as a major health risk factor or outcome in evaluating associations with waist circumference and waist–hip ratio. In populations throughout the world, diabetes apparently increases with overall and abdominal fat gain and obesity development. Comparisons based on diabetes would allow identification of the potential variations in the predictive potential of various cut-off points.

- For any set of cut-off points to be developed, choose the most sound and policy relevant statistical approach to determine cut-off points for waist circumference and waist–hip ratio, and specify the resulting decision rules.

- Develop a schema with different levels of risk and three sets of cut-off points. This could be achieved by linking datasets to diabetes prevalence for countries, and examining whether the recommended cut-off points are appropriate for the reliable identification of disease risk. In addition, it would be helpful to analyse populations with high risk, to ensure that the cut-off points developed are a sensitive measure of risk.

- Alternatively, choose a set of three indicative risk factors (e.g. high blood pressure, elevated cholesterol and elevated blood glucose), whereby a population or group could be identified by waist circumference cut-off points as having one of three levels of risk:
  – Level I: Minimal risk – At this cut-off point, less than 10% of people would have any one of the three indicative risk factors; hence, this would be the lowest level of

risk. The objective is to identify a value that national governments could use for surveillance and to determine the need for public health interventions.
– Level II: Moderate risk – At this cut-off point, there would be a high probability that 80% of people have at least one of the three indicative risk factors, in which case, giving health advice or other appropriate action would be deemed essential. The suggestion was to examine combined datasets (bearing in mind global variation), to judge whether it was possible to arrive at a universal cut-off point to indicate this level of population risk. Issues to consider would be the effects of using 80% as the basis for Level II classification, and whether this value would have the same utility across population groups. Critical analysis of the data should ultimately enable WHO to create a scheme to derive cut-off points tailored for different purposes.
– Level III: Substantial or high risk – At this cut-off point, everyone in the population group would be almost certain to have at least one of the three indicative risk factors. This determination would be based on national or regional datasets that suggest that the individuals in this group will have a doubling of risk compared to low-risk groups. High-risk groups may include subgroups or populations defined by obesity or diabetes prevalence.

• The question of how to cope with transitions in disease risk also needs to be addressed.
Associations of waist circumference or waist–hip ratio with risk factors and diseases may change over time in populations in which incidence of obesity-related diseases is increasing in association with social and economic transitions.

To facilitate the implementation of the proposed next step and carry this process forward, the consultation formed a working group of experts in this area to work closely with WHO.1
The working group comprises academic researchers, clinicians who have expertise in this field, statisticians and data analysts. The working group will also consider gaps in the available global data and items appropriate for future research.

The consultation recommended that the working group be asked to develop and suggest the appropriate methods and criteria for a process for open and transparent analysis and clarification of the relationships between abdominal fat distribution and its measures, and disease risk and health outcomes.

It was agreed that the working group needs access to a wide range of databases worldwide, including the STEPS data within WHO. The consultation recommended that the working group be assisted to gain access to the available datasets.

The consultation urged WHO to view this matter as being of utmost urgency, and to enable completion of the task within a 2-year period. The ultimate recommendations from WHO will depend on whether WHO can obtain representative datasets to permit systematic analysis of all the issues raised in the consultation. Ultimate recommendations from WHO need to take into consideration:
• the various waist circumference and waist–hip ratio criteria that are already in use by national governments, and by national and international medical organizations;
• the potential policy and practical implications associated with any attempts to align diverse cut-offs.

On the other hand, timely and authoritative guidance is needed to ensure that measures that can guide appropriate public health and clinical actions on the problems related to NCDs are brought into full use as quickly as possible. NCDs are rapidly increasing worldwide, particularly in low- and middle-income countries.

The recommended follow-up work to be carried out by the working group that was formed by the consultation has been overtaken by the new guideline development process implemented by WHO as of 1 January 2009. During 2011–2012, the WHO Nutrition Guidance Expert Advisory Group (NUGAG) will take forward the follow-up action recommended by the expert consultation, through its subgroup on Diet and Health.

ANNEX II. PlantLIBRA PFS Consumer Survey's screening questionnaire

PlantLIBRA
EC project number 245199

PFS CONSUMER SCREENING QUESTIONNAIRE
WP1: Intake Estimation of Plant Food Supplements

Interviewer's details:

Name: ________________________ID: ☐☐☐☐ Time of the interview: ☐☐ ☐☐

Date: ☐☐ / ☐☐ / 20☐☐ City: ________________ Location: ____________
day month

Respondent's Age: ☐☐ years **Gender:** 1.☐ Male 2.☐ Female **ID Code:** ☐☐☐☐

Q1. Have you taken any kind of plant/botanical/herbal supplements, any Plant Food Supplement (in Pills/tablets, Gel capsules, …) in the last 12 months?

1. ☐ No - *STOP THE INTERVIEW-MAKE SURE YOU KEEP THE SCREENING DATA*

2. ☐ Cannot recall taking any Plant Food Supplement -> *STOP THE INTERVIEW-MAKE SURE YOU KEEP THE SCREENING DATA*

3. ☐ Yes *(go to Q2 on next page)*

INTERVIEWER: Please use the grid in the next page to record the answers of Q2, Q3, Q4 and Q5

- If respondent is unsure please ask him to show you his/her product(s) to answer the questions
- Please use the decision tree and your briefing instructions to ensure that the product mentioned by respondent is a Plant Food Supplement

Q2. Could you give me the plant name, product name, or the brand of each plant food supplement that you have taken in the last 12 months?
(INTERVIEWER = MULTIPLE ANSWER – PROBE FOR THE NAME OF EACH PLANT FOOD SUPPLEMENT TAKEN IN THE LAST 12 MONTHS –SPECIFCY PLANT NAME(S), PRODUCT NAME AND / OR BRAND)
(Refer to table of Plant Food Supplement to help recall the names)

Q3. In what form do you take *(ASK SEPARATELY FOR EACH NAME MENTIONNED IN Q2),* for example pills, capsules, sachets, drops, etc.? (SINGLE ANSWER PER PRODUCT – READ LIST)

Q4. In the last 12 months, what is the total period of time that you have taken *(ASK SEPARATELY FOR EACH NAME MENTIONED IN Q2)*: less than 3 weeks, at least 3 weeks or more? (SINGLE ANSWER PER PRODUCT – READ LIST))

Q5. During the periods when you have consumed this supplement *(ASK SEPARATELY FOR EACH NAME MENTIONED IN Q2)*, how frequently would you usually take it: less than 1 dose per week or 1 or more doses per week? (SINGLE ANSWER PER PRODUCT – READ LIST)

Q2 - PRODUCT NAME	Q3 –TAKEN FORM	Q4 – TAKEN TIME PERIOD	Q5. TAKEN FREQUENCY
______________________	1.Pills/tablets/lozenges 2.Softgel capsules/pearls 3.Hard capsules 4.Liquid (extract/syrup/drops) 5.Sachets/packets 6.Ampoules 7.Other (specify : __________)	1. Less than 3 weeks (TERMINATE) 2. 3 consecutive weeks or more (ASK Q5) 3. Can't recall (TERMINATE)	1. Less than 1 dose per week (TERMINATE) 2. 1 or more doses per week (ASK Q6) 3. Can't recall (TERMINATE)
______________________	1. Pills/tablets/lozenges 2.Softgel capsules/pearls 3.Hard capsules 4.Liquid (extract/syrup/drops) 5.Sachets/packets 6.Ampoules 7.Other (specify : __________)	1. Less than 3 weeks (TERMINATE) 2. 3 weeks or more (ASK Q5) 3. Can't recall (TERMINATE)	1. Less than 1 dose per week (TERMINATE) 2. 1 or more doses per week (ASK Q6) 3. Can't recall (TERMINATE)
______________________	1. Pills/tablets/lozenges 2.Softgel capsules/pearls 3.Hard capsules 4.Liquid (extract/syrup/drops) 5.Sachets/packets 6.Ampoules 7.Other (specify : __________)	1. Less than 3 weeks (TERMINATE) 2. 3 weeks or more (ASK Q5) 3. Can't recall (TERMINATE)	1. Less than 1 dose per week (TERMINATE) 2. 1 or more doses per week (ASK Q6) 3. Can't recall (TERMINATE)
	1.Pills/tablets/lozenges 2.Softgel capsules/pearls 3.Hard capsules	1. Less than 3 weeks (TERMINATE)	1. Less than 1 dose per week (TERMINATE) 2. 1 or more doses per

____________________	4.Liquid (extract/syrup/drops) 5.Sachets/packets 6.Ampoules 7.Other (specify : __________)	2. 3 weeks or more (ASK Q5) 3. Can't recall (TERMINATE)	week (ASK Q6) 3. Can't recall (TERMINATE)
____________________	1.Pills/tablets/lozenges 2.Softgel capsules/pearls 3.Hard capsules 4.Liquid (extract/syrup/drops) 5.Sachets/packets 6.Ampoules 7.Other (specify : __________)	1. Less than 3 weeks (TERMINATE) 2. 3 weeks or more (ASK Q5) 3. Can't recall (TERMINATE)	1. Less than 1 dose per week (TERMINATE) 2. 1 or more doses per week (ASK Q6) 3. Can't recall (TERMINATE)

INTERVIEWER: Before asking Q6, please check that for at least one product answered in Q2,Q3,Q4,Q5:

Q2 = Is a valid name of Product Food Supplement (double check using the decision tree if needed)
Q3 = The form corresponds to the definition of Plant Food Supplement (no infusion, no teas/tisanes)
Q4 = at least 3 weeks
Q5 = 1 or more doses per week

NOTE: About Q4 - if NO single plant food supplement is taken for 3 (consecutive) weeks or more, BUT the following two situations occur:

- **1 single** plant food supplement, with the **right form** (Q3), consumed in the **dose of 1 or more per week** (Q5), is taken for at least **4 non-consecutive** weeks,

or

- **2 or more** plant food supplements, with the **right form** (Q3), and the **SUM of the consumption period** of the 2 or more products is **EQUAL to 3 or 4 (?) weeks or more**,

…….then the respondent also qualifies as an eligible respondent.

1 ☐ YES – ELIGIBLE RESPONDENT (ASK Q6)
2 ☐ NO – NON-ELIGIBLE RESPONDENT = *STOP THE INTERVIEW-MAKE SURE YOU KEEP THE SCREENING DATA*

Q6. We would like to invite you to participate in a survey about your usage of Plant Food Supplement. Would you be interested in participating in this study and completing our questionnaire?

1 ☐ Yes *(Fill in the Participant Contact Information sheet.)*
2 ☐ No *(Thank you for your participation.) STOP THE INTERVIEW-MAKE SURE YOU KEEP THE SCREENING DATA*

(SHOW CARD TO BE PRINTED SEPARATELY FOR INTERVIEWER TO SHOW DURING SCREENER IF NECESSARY)

Table of top PFS plants and brands

Common Plant Name	Scientific Name	Brand Names commonly sold (adapted to each country): could be mono- or multi-ingredient
Aloe	*Aloe sp.*	
Anise	*Pimpinella anisum*	
Artichoke	*Cynara scolymus*	
Bilberry	*Vaccinium sp.*	
Black cohosh	*Actaea racemosa*	
Boldo	*Peumus boldus*	
Buckthorne	*Rhamnus purshianus*	
Cat’s claw	*Uncaria guianensis*	
Chaste tree berry	*Vitex agnus-castus*	
Chia seed	*Salvia hispanica/Salvia columbariae*	
Comfrey	*Symphytum officinalis*	
Desert Indianwheat	*Plantago ovata*	
Devil’s claw	*Harpagophytum procumbens*	
Dong quai	*Angelica sinensis*	
Evening primrose oil	*Oenothera sp.*	
Fennel	*Foeniculum vulgare*	
Flaxseed	*Linum usitatissimum*	
German Chamomile	*Matricaria recutita*	
Ginkgo	*Ginkgo biloba*	
Ginseng	*Panax ginseng*	
Grapes and grapeseed	*Vitis vinifera*	
Guarana	*Paullinia cupana*	Caffeine pills by SciFit
Horny Goat Weed	*Herba epidemii*	
Horsetail herb	*Equisetum arvense*	
Indian Frankincsense	*Boswellia serrata*	
Kava / Kava-Kava	*Piper methysticum*	
Lavender	*Lavandula angustifolia*	
Lemon Balm	*Melissa officinalis*	
Marigold	*Calendula officinalis*	
Milk thistle	*Sylibum marianum*	
Nettle	*Urtica dioica*	
Olive	*Olea europea*	
Orange	*Citrus sinensis and Citrus aurantium*	
Pale cornflower	*Echinacea pallida Britton*	
Passion flower	*Passiflora incarnata*	
Pycnogenol	French Maritime Pine Extract	
Redclover	*Trifolium pratense*	
Rhubarb - including extract	*Rheum raponticum*	
Rosehip	*Rosa canina*	
Seaweed	*Sargassum homer*	
Sena	*Cassia angustifolia/Cassia senna*	
Soy / Soy Isoflavones	*Glicine max*	
St John's Wort	*Hypericum perforatum*	
Tea	*Camellia sinensis*	Caffeine pills by SciFit
Turmeric	*Curcuma longa*	
Valerian	*Valeriana officinalis*	
Willow bark extract	*Salix sp.*	
Other (specify)		
Other (specify)		

ANNEX III. PlantLIBRA PFS Consumer Survey's main questionnaire

PlantLIBRA
EC project number 245199

PLANT FOOD SUPPLEMENT CONSUMPTION QUESTIONNAIRE

WP1: Intake Estimation of Plant Food Supplements

Interviewer name: __________________ID: ☐☐ Time of the interview: ☐☐ hrs ☐☐

Date: ☐☐ ☐☐ ☐☐☐☐ City: ____________________ day ☐
month year
Location: ________________ ☐

Interviewee ID: ☐☐☐☐

Gender: 1. ☐ Male
2. ☐ Female

Date of birth: ☐☐ / ☐☐ / ☐☐☐☐
day month year

Read card: Thank you for your willingness to participate in this survey on the use of ***PLANT FOOD SUPPLEMENT*** *in European countries. Your contribution will be of great importance to all the consumers in the European community especially when it comes to ensuring that information about these products is available and clearly presented for consumers like yourself.*

As mentioned before, this survey is focused on PLANT FOOD SUPPLEMENTS. We want to know only about plant food supplements that you would eat (not used as topical creams or products for external application). We consider PLANT FOOD SUPPLEMENTS any pre-packaged products that come from plants, herbs or botanicals. On the packaging of these supplements normally you will find the plant ingredient(s) that were used to make these supplements and often, but not always, the word "supplement" is also included on the label. Some examples of PLANT FOOD SUPPLEMENTS are ginseng capsules, ginkgo tablets, echinacea drops, valeriana pills or artichoke pearls. Infusions, dried foods, herbs and spices ***are not*** *PLANT FOOD SUPPLEMENT.*

We will ask you detailed questions about PLANT FOOD SUPPLEMENTS. We will also ask other related information important for the complete evaluation of these supplements. All the information you share with us will be kept strictly confidential and only a number will be used to identify you. Please remember to ask any questions about anything that seems unclear to you.

Questions start on the next page

PLANT FOOD SUPPLEMENT CONSUMPTION PATTERNS

Q1. Could you tell me or show me what PLANT FOOD SUPPLEMENT you currently take or have taken in the last 12 months (C*onsult the top PLANT FOOD SUPPLEMENT plant and brand list below if the respondent cannot recall any names. Complete Q2 to Q20 for each PLANT FOOD SUPPLEMENT identified by the respondent)*

Common Name	Scientific Name	Brand Names commonly sold (adapted to each country): could be mono- or multi-ingredient
Aloe	*Aloe sp.*	
Anise	*Pimpinella anisum*	
Artichoke	*Cynara scolymus*	
Bilberry	*Vaccinium sp.*	
Black cohosh	*Actaea racemosa*	
Boldo	*Peumus boldus*	
Buckthorne	*Rhamnus purshianus*	
Cat’s claw	*Uncaria guianensis*	
Chaste tree berry	*Vitex agnus-castus*	
Chia seed	*Salvia hispanica/Salvia columbariae*	
Comfrey	*Symphytum officinalis*	
Desert Indianwheat	*Plantago ovata*	
Devil’s claw	*Harpagophytum procumbens*	
Dong quai	*Angelica sinensis*	
Evening primrose oil	*Oenothera sp.*	
Fennel	*Foeniculum vulgare*	
Flaxseed	*Linum usitatissimum*	
German Chamomile	*Matricaria recutita*	
Ginkgo	*Ginkgo biloba*	
Ginseng	*Panax ginseng*	
Grapes and grapeseed	*Vitis vinifera*	
Guarana	*Paullinia cupana*	example: Caffeine pills by SciFit
Horny Goat Weed	*Herba epidemii*	
Horsetail herb	*Equisetum arvense*	
Indian Frankincsense	*Boswellia serrata*	
Kava / Kava-Kava	*Piper methysticum*	
Lavender	*Lavandula angustifolia*	
Lemon Balm	*Melissa officinalis*	
Marigold	*Calendula officinalis*	
Milk thistle	*Sylibum marianum*	
Nettle	*Urtica dioica*	
Olive	*Olea europea*	
Orange	*Citrus sinensis and Citrus aurantium*	
Pale cornflower	*Echinacea pallida Britton*	
Passion flower	*Passiflora incarnata*	
Pycnogenol	French Maritime Pine Extract	
Redclover	*Trifolium pratense*	
Rhubarb - including extract	*Rheum raponticum*	
Rosehip	*Rosa canina*	
Seaweed	*Sargassum homer*	
Sena	*Cassia angustifolia/Cassia senna*	
Soy / Soy Isoflavones	*Glicine max*	
St John's Wort	*Hypericum perforatum*	
Tea	*Camellia sinensis*	example: Caffeine pills by SciFit
Turmeric	*Curcuma longa*	
Valerian	*Valeriana officinalis*	
Willow bark extract	*Salix sp.*	
Other (specify)		
Other (specify)		

FIRST PRODUCT - Please ask Q2-1 to Q20-1 for the first product

Q2-1. Plant name and Product name:

____

Q3-1. Brand(s) or manufacturer/distributor name:

____

Q4-1.Product packaging was seen: 1 ☐ Yes 2 ☐ No

Q5-1. For what reason(s)/condition(s) did you take this product?
Please also specify the desired outcome by taking the PLANT FOOD SUPPLEMENT. *(mark **all** that apply)*

1. ☐ Defense system/immunity
2. ☐ Sleeping
3. ☐ Cholesterol
4. ☐ Memory
5. ☐ Relaxing
6. ☐ Body weight
7. ☐ Antioxidant intake
8. ☐ Menopause
9. ☐ Hair /skin
10. ☐ Flu/cold
11. ☐ Stomach/digestive function
12. ☐ Energy/tonics
13. ☐ Vision or hearing
14. ☐ Urinary tract
15. ☐ Mood
16. ☐ Joints and bones
17. ☐ Heart/blood circulation
18. ☐ Other (specify)___________________________
19. ☐ Nothing specific/general health
20. ☐ Don’t know/Not sure

Q6a-1. At each sitting, how much of the supplement do you **usually** take? *(write the **number** given)*

Number/amount usually taken: |___|___|

Q6b-1. And in which form do you **usually** take it? (*mark the applicable **form***)

1. ☐ Pills/tablets/lozenges
2. ☐ Softgel capsules/pearls

3. ☐ Hard capsules
4. ☐ Liquid (extract/syrup/drops)
5. ☐ Sachets/packets
6. ☐ Ampoules
7. ☐ Other (specify) _____________
8. ☐ Not sure

Q7-1. How many times per day, week or month do you take this number/amount (reported in Q6)? *(write the **number** given per day, per month or per week – SINGLE ANSWER)*

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

Q8-1. Thinking about the last 12 months only, for how long of a PERIOD would you take this product at this frequency before you stopped taking it? *(write the **number** given in days, months or weeks – SINGLE ANSWER)*

1. |___|___| days
2. |___|___| weeks
3. |___|___| months
4. Not sure

Q9-1. During the last 12 months, in what months have you taken this supplement? *(mark **all** that apply)*

1. ☐ Jan	7. ☐ July	13. ☐ All year round
2. ☐ Feb	8. ☐ Aug	
3. ☐ Mar	9. ☐ Sep	
4. ☐ Apr	10. ☐ Oct	
5. ☐ May	11. ☐ Nov	
6. ☐ June	12. ☐ Dec	

Q10-1. Why did you decide to take this supplement in the months stated? *(**one** answer only)*

1. ☐ I took it whenever/sporadically
2. ☐ I take it periodically, during those times only
3. ☐ When I had a flare up/worsening of condition
4 ☐ Other reason _________________________
5. ☐ Not sure

Q11-1. Could you tell me for how long in total have you been using this product in your lifetime? *(write the **number** given in days, months or weeks – SINGLE ANSWER)*

1. |___|___| days
2. |___|___| weeks
3. |___|___| months
4. |___|___| years
5. Not sure

Q12-1. When was the last time you took this product? *(**one** answer only)*

1. ☐ less than 24 hrs ago
2. ☐ 24 hrs to less than 72 hrs
3. ☐ 72 hrs to less than 7 days
4. ☐ 7 days to less than 1 month
5. ☐ more than 1 month ago

Q13-1. Who recommended it to you? *(**one** answer only)*

1. ☐ Nobody/myself
2. ☐ Pharmacist
3. ☐ Nurse
4. ☐ Homeopath
5. ☐ Nutritionist/dietitian
6. ☐ Friend/relative
7. ☐ Herbal shop assistant
8. ☐ Doctor/General Physician
9. ☐ TV/radio
10. ☐ Internet/social group
11. ☐ Magazine/newspaper
12. ☐ Other (specify)____________________________
13. ☐ Not sure

Q14-1. Where did you get it from? *(mark **all** that apply)*

1. ☐ Pharmacy
2. ☐ Health/herbal shop
3. ☐ Supermarket/grocery store
4. ☐ Internet
5. ☐ Gym
6. ☐ Network marketing
7. ☐ Other (specify) ___________________________
8. ☐ Not sure

Q15-1. What guidelines or instructions do you follow regarding the dosage when you take this supplement? *(mark **all** that apply)*

1. ☐ Instructions on the packaging
2. ☐ I decide myself how to use the product
3. ☐ Instructions received from the place of purchase
4. ☐ Instructions received from the person that recommended me (mentioned in Q13-1)
5. ☐ Instructions received from friends/family
6. ☐ Instructions received from internet
7. ☐ Other (specify) ___________________
8. ☐ Not sure

Q16-1. Do you think the product helps you? *(**one** answer only)*

1. ☐ Not at all
2. ☐ Rarely
3. ☐ Sometimes
4. ☐ Always
5. ☐ Not sure

Q17a-1. Have you experienced any adverse effects while taking this product?

1. ☐ No -> ASK Q18-1
2. ☐ Yes -> ASK Q17b-1

Q17b-1. If yes, which one? (*please mark all that apply*)

01. ☐ Constipation
02. ☐ Diarrhea
03. ☐ Dizziness
04. ☐ Blurry vision
05. ☐ Stomach upset
06. ☐ Problems sleeping
07. ☐ Drowsiness/Sleepiness
08. ☐ Nausea
09. ☐ Other (specify) ________________________
10. ☐ Not sure

Q18-1. When you started using this product, did you inform your … ?

	YES	NO	NOT SURE
a. General physician	1	2	3
b. Pharmacist	1	2	3

Q19-1. In your opinion, did you receive enough information about this product regarding its….?

	YES	NO	NOT SURE
a. Safety/adverse effects	1	2	3
b. Intended use/indications	1	2	3
c. Recommended dose	1	2	3

Q20-1. Which sources provided you with information about this PLANT FOOD SUPPLEMENT? *(mark **all** that apply)*

01 ☐ Television/radio
02. ☐ Magazines/newspaper
03. ☐ Internet
04. ☐ Specialised/scientific journals
05 ☐ Complementary & Alternative Medicine (CAM) therapist
06. ☐ Doctor/General Physician (GP)
07. ☐ Nutritionist/dietitian

08. ☐ Pharmacist
09. ☐ Brochures from the health department
10. ☐ Brochures from the industry
11. ☐ Books
12. ☐ Friends/relatives
13. ☐ Other (specify)____________________
14. ☐ No source consulted

INTERVIEWER =IF NO OTHER PLANT FOOD SUPPLEMENT TAKEN BY RESPONDENT THEN GO TO Q21, OTHERWISE GO TO NEXT PAGE TO ASK ABOUT THE NEXT PRODUCT

Note of the author of this thesis: In the original questionnaire, Questions 2-20 were repeated up to 5 times, in order to capture details about the consumption of up to 5 products per consumer; however, for the purpose of restricting the length of Annex III, those pages of the questionnaire have not been included.

GENERAL PLANT FOOD SUPPLEMENT QUESTIONS

Q21. You personally, how informed do you feel about plant food supplements in general? ***(one** answer only)*

1. Very well informed
2. Fairly well informed
3. Not very well informed
4. Not at all informed
5. Not sure

Q22. How much in total do you spend on all PLANT FOOD SUPPLEMENS per **month**? (adapt currency to country)

1. Less than 10 Euros
2. 10-49 Euros
3. 50-99 Euros
4. 100 Euros or more
5. Not sure

	Q23. For each of the sources of information that I will name to you now, please tell me how frequently you use them when looking for information on PLANT FOOD SUPPLEMENTS? 1. Not at all 2. Rarely 3. Sometimes 4. Often 5. Always 6. Not Sure						Q24. How reliable do you find these sources when providing you with information on PLANT FOOD SUPPLEMENTS? 1. Not at all reliable 2. Not very reliable 3. Fairly reliable 4. Very reliable 5. Not sure 6. Does not apply					
Sources of information	Not at all	Rarely	Some times	Often	Always	Not Sure	Not at all reliable	Not very reliable	Fairly reliable	Very reliable	Not sure	Does not apply
1. Television/ radio	1	2	3	4	5	6	1	2	3	4	5	6
2. Magazines/ newspaper	1	2	3	4	5	6	1	2	3	4	5	6
3. Internet	1	2	3	4	5	6	1	2	3	4	5	6
4. Specialised/scientific journals	1	2	3	4	5	6	1	2	3	4	5	6
5. Complementary & Alternative Medicine (CAM) therapist	1	2	3	4	5	6	1	2	3	4	5	6
6. Doctor/General Practitioner (GP)	1	2	3	4	5	6	1	2	3	4	5	6
7. Nutritionist/ dietitian	1	2	3	4	5	6	1	2	3	4	5	6
8. Pharmacist	1	2	3	4	5	6	1	2	3	4	5	6
9. Brochures from health department (e.g. available at your pharmacy)	1	2	3	4	5	6	1	2	3	4	5	6
10. Brochures from the industry	1	2	3	4	5	6	1	2	3	4	5	6
11. Books	1	2	3	4	5	6	1	2	3	4	5	6
12. Friends/relatives	1	2	3	4	5	6	1	2	3	4	5	6
13. Other specify : ____________	1	2	3	4	5	6	1	2	3	4	5	6

SOCIODEMOGRAPHIC INFORMATION

Q25. Including yourself, how many people live in your household? *(write the **number** given)*

|___|___| -> IF ANSWER IS 1 GO TO Q27 OTHERWISE GO TO Q26

Q26. Not including yourself, could you tell me how many people live in your household who are…

	Number of people
1.Children younger than 18 years	____
2.Adults 18 years or older	____

Q27. Which best describes your current civil status?

1. Single
2. In a relationship and living with my partner
3. Married
4. Divorced
5. Widowed
6. Refusal to answering

Q28. You personally, were you born in COUNTRY or in another country?

1. In COUNTRY *(go to Q31)*
2. Other (specify) _________________________
3. Refusal to answering

Q29. In what year did you first arrive in COUNTRY?

|___|___|___|___| Year

Q30. Do you feel that your daily diet is similar to the diet in (COUNTRY)? *(**one** answer only)*

1. Yes
2. Sometimes
3. No, my diet is similar to that of another country -> Specify the other country : _________________
4. No, but my diet is not specific to any particular country
5. Not sure
6. Not applicable

Q31. What is the highest level of education you completed? *(**one** answer only)* *(adapted to each country)*

1. No studies
2. Primary school or less
3. Secondary school
4. College degree (2-3 years)
5. University degree (1st cycle/undergraduate)
6. University degree - postgraduate

Q32. What is your current employment status? *(**one** answer only)*

1. Never worked
2. Unemployed
3. Employed
4. Self-employed/freelance
5. House work
6. Student
7. Retired
8. Disabled
9. Other (specify) ___________________________

Q33. In which sector do you work/have you last worked? *(**one** answer only)*

1. Construction
2. Mining and electricity, gas, water
3. Fisheries & Agriculture
4. Education
5. Transport and communications
6. Banking and financial intermediation
7. Hotels and restaurants
8. Public administration
9. Wholesale and retail
10. Health and social work
11. Other community and personal assistance
12. Real estate and business activities
13. Other (specify) __________________________

In FINLAND, skip next question and go to Q35.

Q34. What type of medical/healthcare insurance/coverage do you have access to? *(**one** answer only)*

1. None
2. Public/National
3. Private
4. Both
5. Not sure

CURRENT HEALTH STATUS

Skip Q35.1 (Current weight) if respondent is pregnant and go to Q35.2 (Height)

Q35. What is your……?

1. Current weight: |___|___|___| , |___| kg *(without clothes on)*

2. Height: |___|___|___| cm *(without shoes on)*

Q36. How is your health in general? *(**one** answer only)*

1. Very good
2. Good
3. Neither good nor bad
4. Bad
5. Very bad
6. Not sure

Q37. Have you had any of the following health problems? (adapted to each country's most frequent morbidity conditions) *(mark **all** that apply)*

01. ☐ Hight cholesterol
02. ☐ Asthma
03. ☐ Diabetes
04. ☐ Heart disease
05. ☐ High blood pressure
06. ☐ Liver disease
07. ☐ Chronic bronchitis, emphysema
08. ☐ Long-standing troubles with your muscles, bones and joints (rheumatism, arthritis)
09. ☐ Cataract
10. ☐ Migraine or frequent headaches
11. ☐ Osteoporosis
12. ☐ An allergy (specify) ____________________
13. ☐ Stroke, cerebral haemorrhage
14. ☐ Peptic ulcer (gastric or duodenal)
15. ☐ Gallbladder inflammation/stones
16. ☐ Cancer
17. ☐ Chronic anxiety or depression
18. ☐ Other (specify)________________________
19. ☐ No, none
20. ☐ Not sure

Q38. Have you taken any medications on **a REGULAR basis** during the last 12 months?

1. Yes
2. No

Q39. If "Yes", record the name and **average frequency** of use during the last **12 months**.

MEDICATION 1 - Name:_________________________________

Frequency:

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

MEDICATION 2 - Name:_________________________________

Frequency:

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

MEDICATION 3 - Name:_________________________________

Frequency:

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

MEDICATION 4 - Name:_________________________________

Frequency:

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

MEDICATION 5 - Name:_________________________________

Frequency:

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

AWARENESS OF FOOD SUPPLEMENT USE

Q40. Other than PLANT FOOD SUPPLEMENT, have you taken any of the following supplements **on a regular basis** in the **last 12 months**? *(mark **all** that apply)*

1. ☐ Vitamins (A, B, D, E, etc.)
2. ☐ Minerals (eg. potassium, calcium)
3. ☐ Amino acids
4. ☐ Enzymes (eg. lactase)
5. ☐ Prebiotics (eg. oligosaccharides, fibre)
6. ☐ Probiotics (eg. bifidobacteria, yeasts)
7. ☐ Fatty acids (eg. fish oil)
8. ☐ Other_______________________________
9. ☐ No *(go to Q42*)
10. ☐ Not sure *(go to Q42)*

Q41. *Record the name of the product and the **average frequency** of use in the last **12 months** of each product.*

SUPPLEMENT 1 - Name:________________________________

Frequency:

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

SUPPLEMENT 2 - Name :________________________________

Frequency :

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

SUPPLEMENT 3 - Name :________________________________

Frequency :

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

SUPPLEMENT 4 - Name :________________________________

Frequency :

1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure

SUPPLEMENT 5 - Name :________________________________

Frequency :

1. |___|___| per day

2. |___|___| per week
3. |___|___| per month
4. Not sure

USE OF ALTERNATIVE OR COMPLIMENTARY HEALTHCARE

Q42. In the past year, have you seen any of the following practitioners? (*If yes, mark* ***how many times*** *was the practitioner visited in the last* ***12 months****)*

	No visit	1 to 2 visits per year	3 or more visits per year
1. Acupuncturist	*1*	*2*	*3*
2. Chiropractor	*1*	*2*	*3*
3. Homeopath	*1*	*2*	*3*
4. Herbalist	*1*	*2*	*3*
5. Massage therapist	*1*	*2*	*3*
6. Traditional/faith healer	*1*	*2*	*3*
7. Reflexologist	*1*	*2*	*3*
8. Other Specify : ___________ _____________________	*1*	*2*	*3*

FOOD HABITS

Q43. Do you follow any special diet(s) at the moment which would cause you to avoid certain foods?

1. No (go to Q47)
2. Yes

Q44. Please, indicate the special diet that you follow ? (*mark* ***all*** *that apply*).

1. ☐ Type 1 diabetes
2. ☐ Type 2 diabetes
3. ☐ Gestational diabetes
4. ☐ High blood pressure
5. ☐ Overweight
6. ☐ Cholesterol
7. ☐ Celiac disease
8. ☐ Lactose intolerance
9. ☐ Food allergy_________________________
10. ☐ Food allergy_________________________
11. ☐ Food allergy ________________________
12. ☐ Food allergy ________________________
13. ☐ Food allergy ________________________
14. ☐ Vegetarian, including

a) ☐ dairy
b) ☐ eggs
c) ☐ fish
d) ☐ none of these

15.☐ Other ____________________________
16.☐ Other ____________________________

Q45. When did you start the diet?
1. <1 year ago
2. 1-3 years ago
3. 4-5 years ago
4. 6-10 years ago
5. >10 years ago

Q46. Who prescribed/recommended this diet to you?
1. Myself/friend/relative
2. General practitioner/specialist
3. Nutritionist/dietician
4. Nurse
5. Other

Q47. In the last 12 months, how often have you consumed these foods?

FOOD TYPE	FREQUENCY
01. Red meat/sausages/cold meat	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
02. White/lean meat	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
03. Fish and seafood	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
04. Eggs	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
05. Dairy (milk, yogurt, cheese)	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
06. Bread or cereals (rice, pasta…)	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
07. Fruits	1. |___|___| per day 2. |___|___| per week 3. |___|___| per month 4. Not sure
08. Vegetables	1. |___|___| per day 2. |___|___| per week

<table>
<tr><td></td><td>3. |___|___| per month
4. Not sure</td></tr>
<tr><td>09 .Fruit/vegetable juices, concentrates</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>10. Legumes/pulses</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>11. Fats</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>12. Vegetable oils (olive, canola, etc.)</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>13. Nuts and seeds</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
</table>

<table>
<tr><td>14. Fast food</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>15. Pastries/sweets</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>16. Soft drinks (still/sparkling)</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>17. Alcoholic drinks</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>18. Coffee</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>19. Tea & fruit teas</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>20. Herbal tea</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
<tr><td>21. Other - Specificy :
____________________________________</td><td>1. |___|___| per day
2. |___|___| per week
3. |___|___| per month
4. Not sure</td></tr>
</table>

Q48. How often do you consume organic foods? *(**one** answer only)*

1. Always
2. Most of the time when possible
3. Sometimes
4. Rarely
5. Never

SMOKING HABITS

Q49. From the following situations, which describes you with respect to smoking? Please include cigarettes, cigars and pipes when thinking about your answer. *(**one** answer only)*

1. Currently I don't smoke *(go to Q50)*
2. Currently I smoke occasionally (less than 1/day) *)*
3. Currently I smoke every day (1 or more/day) *(go to Q51)*

Q50. Have you ever smoked in the past? *(**one** answer only)*

1. No, I've never smoked *(go to Q51)*
2. Yes, I smoked less than 1/day for less than 6 months
3. Yes, I smoked less than 1/day during 6 or more months
4. Yes, I smoked more than 1/day for less than 6 months
5. Yes, I smoked more than 1/day for 6 or more months

Q51. How long ago did you stop smoking? *(**one** answer only)*

1. Less than 6 months ago
2. 6 to 12 months ago
3. More than 1 year ago

IPAQ-PHYSICAL ACTIVITY QUESTIONNAIRE

The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and outside work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

Q52. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

____ days
9 . No vigorous physical activities *(go to Q54)*

Q53. How much time did you usually spend doing **vigorous** physical activities on one of those days?

|___|___| **hours per day**
|___|___| **minutes per day**
99. Don’t know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

Q54. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

____ days
9 . No moderate physical activities *(go to Q56)*

Q55. How much time did you usually spend doing **moderate** physical activities on one of those days?

|___|___| **hours per day**
|___|___| **minutes per day**
99. Don’t know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

Q56. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

____ days
9 . No walking *(go to Q58)*

Q57. How much time did you usually spend **walking** on one of those days?
|___|___| **hours per day**
|___|___| **minutes per day**
99. Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

Q58. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

|___|___| **hours per week day**
|___|___| **minutes per week day**
99. Don't know/Not sure

(End of the questionnaire. Thank the interviewer for her/his participation)

ANNEX IV. Articles and posters

ANNEX IVa - Article:

Obesity and overweight trends in Catalonia, Spain (1992-2003): gender and socio-economic determinants.

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Obesity and overweight trends in Catalonia, Spain (1992–2003): gender and socio-economic determinants

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Abstract

Objective: To evaluate the trends of overweight and obesity prevalences in the population of Catalonia, Spain, aged 18–75 years, and the influence of socio-economic determinants on these prevalence trends.
Design: Analysis based on data from two representative population-based cross-sectional surveys.
Setting: Data from the two Evaluations of Nutritional Status in Catalonia (ENCAT 1992–93 and ENCAT 2002–03), Spain. Weights and heights were obtained by direct measurement in standardised conditions by trained interviewers. Overweight and obesity were defined using body mass index (BMI) and waist circumference (WC), categorised according to WHO criteria.
Subjects: In total, 1015 men and 1233 women from ENCAT 1992–93, and 791 men and 924 women from ENCAT 2002–03.
Results: Mean BMI and mean WC were higher in males in 2002–03 as compared to 1992–93, while for females mean BMI was lower except for the youngest group, and mean WC was higher. In men, overall BMI overweight prevalence remained stable (from 44.1% to 43.7%), while obesity increased (from 9.9% to 16.6%); total WC overweight remained stable (from 21.7 to 23.8%), while WC obesity increased (from 13.1% to 24.4%). In women, overall BMI overweight increased (from 29.1% to 30.1%), whereas BMI obesity remained stable (from 15.0% to 15.2%); total WC overweight decreased (from 21.8% to 17.7%), while WC obesity increased (from 24.5% to 31.1%). The socio-economic and education variables had an influence on BMI and WC overweight and obesity rates mainly on females in both surveys and on the youngest men only in the 1992–93 survey.
Conclusions: Ten-year trends indicate that Catalan males are getting bigger overall (BMI) and around the waistline (WC), while Catalan females only have bigger waistlines (WC). BMI male obesity prevalence has overtaken that of females. WC obesity continues to be more prevalent among females than males.

Keywords
Obesity
Overweight
Prevalence
Adults
Socio-economic determinants
Cross-sectional survey
Trends

Overweight and obesity are recognised as public health problems worldwide and as major causes of preventable ill health[1]. Total obesity is the sixth most important risk factor contributing to the overall burden of disease worldwide, being a major risk factor for chronic non-communicable diseases such as hypertension, coronary heart disease, type 2 diabetes, dyslipidaemia, as well as to some hormone-dependent cancers[2]. Abdominal obesity is a strong predictor of coronary heart disease and related risk factors[3]. Overweight and obesity also have an important health cost associated with them[2].

The World Health Organisation (WHO) recently reported 1.1 billion overweight individuals and 300 million obese individuals[1], 10% of which are overweight or obese children[4]. Overweight and obesity prevalence rates are increasing in both developed and developing societies[1]. The WHO reported that, since 1980, obesity prevalence rates have increased threefold in Northern

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America (in the United States over 65% of adults are now overweight or obese[5]), the United Kingdom, Central and Eastern Europe, Pacific Islands, Australia and China[1].

In Spain, adult, adolescent and child obesity prevalence has also increased in the last decade[6,7]. The group of children aged between 6 and 13 years and the group of women aged over-45 years are the groups with the highest risk of obesity; obesity prevalence is higher among males during years of growth and development[6,7], while in the over 45-year group it is significantly higher in females[6,8]. In a recent study in Southern Spain, the authors found that a larger proportion of men were overweight compared to women, but the opposite was found for obesity[9]. In 2004, the results from the DORICA Study[10] showed that the obesity prevalence of the North-Eastern region of Spain (which includes Catalonia) was 8.5% for men and 13.8% for women, which were the lowest out of the eight regions included in the study[6].

Numerous studies have shown that obesity is more frequent in the less socially advantaged population groups, regardless of the variable used to classify socio-economic status (SES); these differences in the prevalence of obesity by SES have been observed in both men and women, but are stronger and more consistent in women[11]. The WHO's MONICA Study showed that the prevalence of obesity is higher among adults and children of low SES[12]. In Spain, in 1987, a group of researchers found a higher prevalence of obesity among the population of a lower educational level[8]; in the period 1987–97, the same researchers found a higher obesity prevalence in individuals with elementary education, and that the obesity prevalence proportion associated with elementary education increased in women and decreased in men[13]. Moreover, the SEEDO'97 Study in Spain showed higher obesity rates in men and women with low educational level, and also that older women with low educational level and low income seemed to be the most susceptible group to weight gain[2]. Adding to this evidence, a significant inverse relationship between SES and overweight and obesity was found by the AVENA (*Alimentación y Valoración del Estado Nutricional de los Adolescentes Españoles*) Study[14], although only in male adolescents.

Overweight and obesity also have a sociodemographic component. In this respect, the SEEDO'97 Study in Spain also showed differences in the distribution of the obesity prevalence by area of residence and geographical zones[15].

Other well-known factors that influence the development of obesity are physical inactivity[16,17], over-consumption of energy-dense diets (which has been shown to be associated with low SES)[18] and genetic factors (although some authors do not agree to this)[5].

The objective of the present paper is to evaluate the trends (1992–2003) of overweight and obesity prevalences in the 18–75-year-old population of Catalonia, Spain, and the influence of socio-economic and socio-demographic determinants on these prevalence trends.

Material and Methods

Sample and subjects

The data analysed in this paper belong to the 1992–93 and the 2002–03 cross-sectional Evaluations of the Nutritional Status of the Catalan Population (ENCAT 1992–93 and ENCAT 2002–03)[15,19]. ENCAT is a regional survey carried out periodically by the Department of Health of the Catalan Government and co-ordinated by the Centre for Research on Community Nutrition of the University of Barcelona. The theoretical random sample population and sample size have been described elsewhere[15,19], comprising the population source of residents in the official census. The samples were stratified according to household and randomised into sub-groupings with municipalities being the primary sample units, and individuals within these municipalities comprising the final sample units. The valid response rate for the first survey was 69% and for the second 65%.

Adults from each representative sample within the age of 18–75 years were included in the analysis of this study (n in ENCAT 1992–93 = 2248 and n in ENCAT 2002–03 = 1715).

Data collection procedures and variables of the study

In both surveys, dietitians were trained on standardisation of criteria and methodology before data collection, in order to reduce inter-observer measurement variability. The data were collected from 1992 to 1993 and from 2002 to 2003 through questionnaires and anthropometric measurements during a home interview.

In order to analyse the influence of the socio-economic determinants on the prevalence of overweight and obesity, the following variables were used and rearranged according to the following categories[2]:

1. Socio-economic level (SEL) (occupation of the subject): (a) *low*: the non-classifiable, army, agricultural sector, service sector and non-qualified labourers; (b) *medium*: qualified labourers, foremen, rest of administrative, commercial and technical staff and medium-level technicians; (c) *high*: high-level technicians, directors/managers, self-employed professionals, business owners or self-employed individuals without staff, business owners or self-employed individuals with staff.
2. Education level of the subject and of the family's head member (ELS and ELH): (a) *low*: primary school incomplete or illiterate (<6 years at school); (b) *medium*: primary school completed, secondary school or further education (6–12 years of education); (c) *high*: high school, college or university degree (>12 years of education).

The sociodemographic determinants included (1) gender, (2) age group (18–24, 25–44, 45–64 and 65–75 years) and (3) population of residence size (<10,000 inhabitants, 10,000–100,000 inhabitants and >100,000 inhabitants).

Anthropometric measurements

Body mass index

Weight and height were measured with a portable spring scale and a metric tape (Kawe© model). The individuals were measured in standardised conditions, wearing underwear and no shoes. Weight was measured in kilograms, scale measurement error ±100 g. Height was measured standing and head in the Frankfurt horizontal position, expressed in centimetres, instrumental measurement error ±0.1 cm. Body mass index (BMI) was calculated using weight and height and categorised according to WHO criteria[20] so that overweight was defined as BMI $\geq$25.0 to BMI <30.0 kg m^{-2} and obesity as BMI $\geq$30 kg m^{-2}.

Waist circumference

Waist circumference (WC) was measured with a non-elastic metric tape halfway between the lower border of the ribs and the iliac crest on a horizontal plane. Measurements were recorded to the nearest 0.1 cm and categorised according to WHO criteria, so that men with a WC 94.0–101.9 cm and women with a WC 80.0–87.9 cm were classified as overweight, and men with a WC $\geq$ 102.0 cm and women with a WC $\geq$ 88.0 cm were classified as obese[20].

Statistical analysis

All analyses were performed with SPSS 12.0. Proportions of overweight and obesity were estimated for each sample separately and stratified by gender and age (to control for its potential confounding effects). The age distribution of the whole Catalan population in 1992–93 was used as a reference. The proportions from the two surveys were compared using the χ^2 statistic test and the means were compared using the *t*-test, considering *P*-values <0.05 for significance.

Results

The sample characteristics of the two surveys are presented in Table 1: the total number of subjects by gender, age group and each socio-economic/sociodemographic variable category.

Table 2 shows the mean, standard deviations and 5th–95th percentiles of BMI and WC by gender and age group. In 2002–03, male mean BMI was higher than in 1992–93, although the observed difference was significant only for individuals aged 25–44 years (from 25.2 to 25.9) and 45–64 years (from 26.7 to 27.4), and male mean WC was significantly higher in all age groups; for females the observed decreasing trends in mean BMI in most age groups (except for the youngest) were not significant, while mean WC was significantly higher only in the youngest (from 70.3 to 72.7) and eldest (from 92.2 to 95.3) individuals. These results are shown in Figs 1 and 2, which also show how mean BMI and WC increase as age progresses in both genders. Percentiles 50, 75 and 95 of BMI showed increases in males from all age groups and decreases in females (except for the youngest group). As for WC, percentiles 50, 75 and 95 showed increases in males and females of all age groups.

Table 3 shows overall by-gender and by-survey BMI and WC overweight and obesity prevalences; it can be observed that the overall prevalence of BMI obesity increased significantly only in males (6.7 percentage points, from 9.9% to 16.6%) in the 10-year period, while that of WC obesity increased in both sexes (11.3 percentage points for males – from 13.1% to 24.4%, and 6.6 for females – from 24.5% to 31.1%). Table 3 also shows BMI and WC overweight and obesity prevalences when age, SEL, education level and population of residence size are considered.

When considering the variable ‘age’, Table 3 shows that in ENCAT 1992–93, the highest prevalence of BMI overweight was found in both males and females aged 45–64 years, which was also the case for female but not for male WC overweight; while in ENCAT 2002–03, only an increase in female BMI overweight and male WC overweight were observed with progressing age. Regarding obesity, both surveys showed an increase in the prevalence of BMI and WC obesity with progressing age in both sexes (note the high prevalence of WC obesity among the eldest men and women in 2002–03, 49.6% and 70.9% respectively). The between-survey comparison showed significant changes only in male BMI overweight and male WC obesity rates, demonstrating alarming increases in the latter rates (i.e. from 1.3% to 6.0% in the 18–24-year-old group).

Regarding the variable ‘socio-economic level’ (SEL), the differences observed in BMI and WC overweight and obesity prevalences of the different SEL groups were significant only in females of both surveys, WC obesity being highest in the low SEL group (Table 3). In ENCAT 1992–93, SEL was inversely related to the prevalence of BMI obesity, but only significantly in females; this inverse relationship was not observed among SEL groups in ENCAT 2002–03. WC obesity was only inversely related with SEL in females of both surveys and the differences among SEL groups were significant (Table 3). The between-survey comparison showed significant increases in male BMI and WC obesity (from 8.3% to 16.5% and from 13.3% to 26.3%) and female WC obesity (from 15.3% to 19.3%).

With regard to the variable ‘education level of the subjects’ (ELS), in ENCAT 2002–03, Table 3 shows an

Table 1 Sample characteristics of the two ENCAT surveys

Variables	ENCAT 1992–93 *n*	ENCAT 1992–93 %	ENCAT 2002–03 *n*	ENCAT 2002–03 %
Gender				
Males	1015	45.2	791	46.1
Females	1233	54.8	924	53.9
Age group (years)				
18–24	526	23.4	276	16.1
25–44	801	35.6	654	38.1
45–64	668	29.7	557	32.5
65–75	253	11.3	228	13.3
BMI* ($kg\,m^{-2}$)				
<18.5 (underweight)	37	1.6	33	1.9
18.5 to <25.0 (normal)	1119	49.8	787	45.9
25.0 to <30.0 (overweight)	807	35.9	624	36.4
≥30.0 (obese)	285	12.7	271	15.8
WC† (cm)				
Normal	1312	59.4	878	52.2
Overweight	484	21.5	349	20.0
Obese	430	19.1	477	27.8
Socio-economic level (SEL – occupation)				
Low	666	30.5	258	15.2
Medium	964	44.1	627	36.9
High	557	25.5	812	47.8
Education level subject (ELS)				
Low	486	21.6	233	13.6
Medium	1154	51.3	861	50.3
High	608	27.0	618	36.1
Education level head of family (ELH)				
Low	654	29.1	264	15.5
Medium	1145	50.9	925	54.3
High	449	20.0	513	30.1
Population size (inhabitants)				
<10,000	294	13.1	379	22.1
10,000–100,000	604	26.9	541	31.5
>100,000	1350	60.1	795	46.4
Total (*n*)	2248	100.0	1715	100.0

*Body mass index – according to WHO classification (1998).
†Waist circumference – according to WHO classification (1998): normal: <94 cm for males and <80 cm for females; overweight: ≥94 to <102 cm for males and ≥80 to <88 cm for females; obese: ≥102 cm for males and ≥88 cm for females.
ENCAT – Evaluation of Nutritional Status in Catalonia.

inverse relationship with BMI overweight and obesity prevalence, but with differences among ELS groups only significant in females (note a female BMI obesity prevalence of 36.6% in the lowest ELS group); this inverse relationship was observed between ELS and male and female WC obesity but not WC overweight (note the high male and female WC obesity rates in the lowest ELS group, 34.3% and 69.5% respectively). The between-survey comparison revealed significant differences in both BMI and WC overweight and obesity for both genders. It is worth noticing that while male and female WC overweight seem to have increased among the highest ELS group (from 15.5% to 23.9% and from 11.8% to 14.9% respectively), female WC obesity prevalence in the lowest ELS group increased by 20 percentage points (from 49.3% to 69.5%).

The variable 'education level of the family head member' (ELH) showed in ENCAT 2002–03 a significant inverse relationship with BMI overweight, BMI obesity and WC obesity in females (Table 3). Females whose family head member had a medium education level presented the highest WC overweight prevalence compared to females whose family head member had a low or high ELH (23.9% in 1992–93 and 19.0% in 2002–03). The between-survey comparison revealed significant differences in both BMI and WC overweight and obesity for both genders. Male and female BMI overweight, male and female BMI obesity, male WC overweight and male and female WC obesity rates increased in the low and high ELH groups, while in the medium ELH group the increase was only observed in male BMI overweight (from 9.6% to 17.5%) and male and female WC obesity (from 12.9% to 24.9% and from 23.3% to 30.2% respectively). The difference of 27 percentage points in female WC obesity prevalence in the low ELH group is worth noticing (from 35.1 in ENCAT 1992–93 to 61.9% in ENCAT 2002–03).

Regarding 'population of residence size', only ENCAT 2002–03 differences observed in female WC overweight and obesity were significant ('within-survey comparison',

Table 2 Mean, standard deviation and percentiles of body mass index and waist circumference, by gender, age and survey (ENCAT 1992–93 and ENCAT 2002–03)

Gender	Age (years)	*n*		Mean			SD		P5		P25		P50		P75		P95	
		1992–93	2002–03	1992–93	2002–03	*t*-Test†	1992–93	2002–03	1992–93	2002–03	1992–93	2002–03	1992–03	2002–03	1992–93	2002–03	1992–93	2002–03
Body mass index (kg m^{-2})																		
Males	18–24	237	116	23.4	24.0	ns*	2.8	3.8	19.2	19.6	21.4	21.4	22.9	23.2	25.2	25.7	28.7	32.5
	25–44	359	309	25.2	25.9	s**	3.1	3.7	20.4	20.3	23.1	23.2	25.0	25.4	27.1	28.1	31.1	33.0
	45–64	312	250	26.7	27.4	s	3.4	3.4	21.4	22.0	24.6	25.5	26.5	27.3	28.6	29.1	31.9	33.2
	65–75	107	116	26.9	27.7	ns	3.5	3.6	21.7	22.6	24.8	24.8	26.2	27.6	29.8	30.4	33.7	33.6
Females	18–24	289	160	22.0	22.1	ns	2.6	3.1	18.5	18.2	20.1	19.9	21.5	21.5	23.6	24.3	26.6	27.8
	25–44	442	345	24.2	23.9	ns	4.1	4.1	19.3	18.9	21.5	20.9	23.5	23.0	26.1	26.1	31.2	31.2
	45–64	356	307	27.7	26.9	ns	4.5	4.7	21.2	19.9	24.7	23.6	27.2	26.3	30.2	29.8	36.0	35.3
	65–75	146	112	28.9	28.3	ns	6.2	4.4	20.5	19.3	25.2	25.8	28.7	28.6	31.4	30.5	38.7	36.3
Waist circumference (cm)																		
Males	18–24	237	116	81.8	84.6	s	8.5	12.0	70.0	70.0	76.0	76.9	81.0	83.0	86.5	90.5	97.1	105.5
	25–44	359	309	88.4	91.5	s	9.1	11.1	74.9	74.0	82.0	83.9	88.3	91.0	94.4	97.6	104.1	110.7
	45–64	312	250	95.2	97.7	s	10.5	10.9	79.6	81.3	88.3	92.0	95.0	97.1	102.0	104.3	111.0	117.5
	65–75	107	116	97.0	102.8	s	9.3	10.8	78.7	83.6	91.6	96.0	97.5	102.0	103.2	111.0	111.6	121.4
Females	18–24	289	160	70.3	72.7	s	7.0	7.9	60.6	62.0	66.0	67.0	69.0	71.0	74.0	77.2	84.0	87.0
	25–44	442	345	77.4	78.8	ns	9.9	11.3	64.0	65.0	71.0	70.8	75.5	76.0	83.0	85.0	95.6	100.0
	45–64	356	307	87.1	86.9	ns	10.9	12.8	69.1	68.1	80.0	77.0	85.5	87.0	94.0	95.5	105.9	110.5
	65–75	146	112	92.2	95.3	s	10.0	11.6	76.5	74.0	84.5	88.0	91.8	95.0	99.2	104.9	111.5	114.0

*ns – non-significant difference; **s – significant difference (*P*-value <0.05).
†*t*-Test used for between-survey comparison of BMI and WC means.
SD = standard deviation; *P* = percentile; ENCAT – Evaluation of Nutritional Status in Catalonia

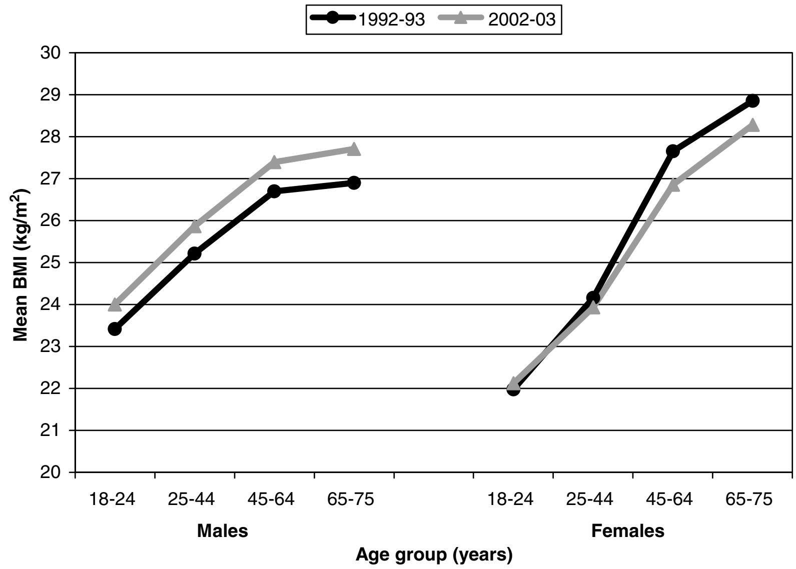

Fig. 1 Mean BMI by gender, age and survey year (ENCAT 1992–93 and 2002–03) (BMI – body mass index; ENCAT – Evaluation of Nutritional Status in Catalonia)

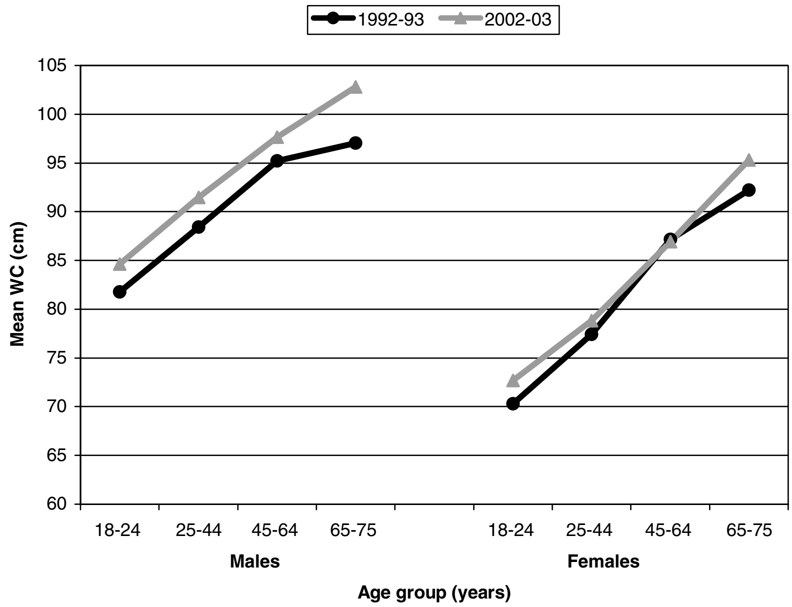

Fig. 2 Mean WC by gender, age and survey year (ENCAT 1992–93 and 2002–03) (WC – waist circumference; ENCAT – Evaluation of Nutritional Status in Catalonia)

Table 3). The between-survey comparison showed significant differences in all prevalences except for males BMI and WC obesity; it is worth mentioning that, in the <10,000 inhabitants group, while female BMI and WC overweight rates decreased (from 32.5 to 27.8% and from 22.5 to 12.9%, respectively), female BMI and WC obesity rates increased (from 15.6 to 18.0 and from 31.1 to 38.6%, respectively).

Table 4 shows how the ENCAT 2002–03 BMI and WC overweight and obesity prevalences change when adjusting by the ENCAT 1992–93 SEL, ELS, ELH and population of residence size distributions. It is apparent

Table 3 Overweight and obesity prevalence (BMI and WC) by gender, survey year (ENCAT 1992–93 and ENCAT 2002–03), socio-economic and sociodemographic characteristics

	BMI overweight†				BMI obesity‡				WC Overweight§				WC obesity¶			
	Males		Females		Males		Females		Males		Females		Males		Females	
Variables	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %
Overall prevalence (crude)‖	44.1	43.7	29.1	30.1	9.9	16.6	15.0	15.2	21.7	23.8	21.8	17.7	13.1	24.4	24.5	31.1
Between-survey comparison	s*		ns**		s		ns		s		s		s		s	
Age (years)																
18–24	27.0	19.8	7.3	18.1	2.5	6.9	1.7	1.3	7.7	7.8	7.3	11.9	1.3	6.0	1.7	2.5
25–44	43.2	41.7	26.7	22.9	7.0	13.3	6.6	8.7	18.8	20.3	19.3	15.5	6.2	16.3	14.0	20.7
45–64	56.4	60.0	44.7	37.5	14.7	18.4	27.8	23.8	30.9	31.2	35.8	22.4	24.8	31.2	39.2	43.4
65–75	49.5	37.9	41.8	49.1	21.5	31.0	35.6	31.3	35.5	33.0	23.6	20.0	28.0	49.6	65.3	70.9
Between-survey comparison	s		ns		ns		ns		ns		ns		s		ns	
Socio-economic level (SEL – occupation)																
Low	44.7	44.0	28.6	33.3	11.0	16.5	23.4	19.9	23.5	23.5	23.3	19.0	11.4	25.8	32.0	39.0
Medium	44.8	45.0	30.7	28.2	10.2	16.4	13.3	11.2	22.2	25.1	23.1	16.5	14.2	21.5	22.9	26.0
High	43.0	42.6	25.7	25.2	8.3	16.5	5.8	11.2	18.6	21.9	17.8	17.1	13.3	26.3	15.3	19.3
Within-survey comparison	ns	ns	s	s	ns	ns	s	s	ns	ns	s	s	ns	ns	s	s
Between-survey comparison	s		s		s		ns		s		s		s		s	
Education level subject (ELS)																
Low	53.7	50.5	41.9	45.5	19.1	21.2	32.6	36.6	31.9	28.3	26.7	17.6	21.8	34.3	49.3	69.5
Medium	42.9	43.9	31.4	32.5	9.6	17.6	12.6	15.7	21.5	22.7	24.4	19.7	12.2	25.7	21.8	34.1
High	40.3	41.6	12.3	20.5	4.4	13.6	2.9	5.7	15.5	23.9	11.8	14.9	9.1	19.0	5.9	11.6
Within-survey comparison	s	ns	s	s	s	ns	s	s	s	s	s	s	s	s	s	s
Between-survey comparison	s		s		s		s		s		s		s		s	
Education level head of family (ELH)																
Low	42.1	45.9	32.7	40.1	13.8	17.2	23.9	33.8	22.5	26.2	22.1	16.5	15.2	29.5	35.1	61.9
Medium	46.7	42.9	31.1	31.5	9.6	17.5	13.5	13.4	23.8	22.1	23.9	19.0	12.9	24.9	23.3	30.2
High	41.0	44.8	18.1	22.8	5.1	14.5	5.2	9.2	15.8	25.8	15.4	16.0	10.7	20.4	11.0	17.5
Within-survey comparison	s	ns	s	s	s	ns	s	s	s	ns	s	s	s	ns	s	s
Between-survey comparison	s		s		s		s		s		s		s		s	
Population size (inhabitants)																
<10,000	44.3	46.6	32.5	27.8	12.1	16.7	15.6	18.0	21.4	22.1	22.5	12.9	15.7	26.2	31.1	38.6
10,000–100,000	42.2	44.6	28.0	33.6	11.6	15.7	15.2	15.1	20.9	25.0	20.9	20.0	12.7	24.2	25.4	32.1
>100,000	45.0	41.8	28.9	28.8	8.6	17.1	14.8	13.8	22.1	23.7	22.0	18.4	12.6	23.7	22.7	26.8
Within-survey comparison	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns	s	ns	ns	ns	s
Between-survey comparison	s		s		ns		s		s		s		ns		s	

* s: χ^2 test – significant difference ($P \leq 0.05$); **ns: χ^2 test – non-significant difference.
†BMI 25.0 to $\leq$30.0 kg m^{-2};
‡BMI $\geq$30.0 kg m^{-2};
§WC 94 to $<$102 cm for males and 80 to $<$88 cm for females.
¶WC $\geq$ 102 cm for males and $\geq$88 cm for females.
‖See Table 4 for adjusted prevalences.
ENCAT – Evaluation of Nutritional Status in Catalonia; BMI – body mass index; WC – waist circumference.

Table 4 Overall crude and adjusted overweight and obesity prevalences (BMI and WC), by gender and survey year (ENCAT 1992–93 and ENCAT 2002–03)

Variables	BMI overweight*				BMI obesity†				WC overweight*				WC obesity†			
	Males		Females		Males		Females		Males		Females		Males		Females	
	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2002–03 %	1992–93 %	2000–03 %
Overall crude prevalence	44.1	43.7	29.1	30.1	9.9	16.6	15.0	15.2	21.7	23.8	21.8	17.7	13.1	24.4	24.5	31.1
2002–03 prevalence standardised by 1992–93 SEL‡ distribution (SR§)	44.1	44.1	29.1	29.4	9.9	16.5	15.0	13.9	21.7	23.9	21.8	17.5	13.1	24.1	24.5	28.3
2002–03 prevalence standardised by 1992–93 ELS¶ distribution (SR)	44.1	45.4	29.1	33.4	9.9	17.8	15.0	19.6	21.7	24.7	21.8	17.9	13.1	26.7	24.5	39.2
2002–03 prevalence standardised by 1992–93 ELH‖ distribution (SR)	44.1	44.3	29.1	31.9	9.9	16.7	15.0	18.6	21.7	24.4	21.8	17.5	13.1	25.2	24.5	36.8
2002–03 prevalence standardised by 1992–93 pop. size distribution (SR)	44.1	45.4	29.1	33.4	9.9	17.8	15.0	19.6	21.7	23.7	21.8	17.4	13.1	25.0	24.5	33.0

*BMI 25 to $<30\,\text{kg m}^{-2}$ and WC 94 to <102 cm for males and 80 to <88 cm for females, according to WHO classification (1998).
†BMI $\geq 30\,\text{kg m}^{-2}$ and WC ≥ 102 cm for males and ≥ 88 cm for females, according to WHO classification (1998).
‡SEL – socio-economic level.
§SR – standardised rate.
¶ELS – education level of the subject.
‖ELH – education level of the family head member.
ENCAT – Evaluation of Nutritional Status in Catalonia; BMI – body mass index; WC – waist circumference.

that male and female BMI obesity increased to its highest when standardised by the ENCAT 1992–93 ELS and population size (from 16.6% to 17.8% and from 15.2% to 19.6%, respectively), while male and female WC obesity increased to its highest when standardised by the ENCAT 1992–93 ELS (from 24.4% to 26.7% and from 31.1% to 39.2%, respectively). Male and female BMI and WC obesity decreased when adjusted by the ENCAT 1992–93 SEL distribution.

Discussion

The WHO recognises that the main limiting factors when comparing epidemiological studies on the prevalence of overweight and obesity are the following: the different criteria to define the cut-offs, the variation in age groups considered, the time interval for collection of data and study comparisons based on reported weight and height[20]. This study is based on the 1992–93 and 2002–03 ENCAT surveys, which were carried out on representative random samples of the Catalan population. Both surveys used the same anthropometric measurement procedures (weight, height and WC were measured instead of reported) and socio-economic factors, and allow for comparison of the same age groups (18–75 years).

The WHO has recommended BMI as a good index of total overweight and obesity[20], although it gives no information about body fat distribution, while WC reflects abdominal visceral fat distribution. Nevertheless, the two measures are highly correlated[21]. It has been shown that changes in WC accompany changes in cardiovascular risk factors especially in the elderly[22]. Research has also shown that WC can also predict morbidity and mortality, considering it a better measure of obesity than BMI, since it is a simple and easy measurement[23]; WC is even more strongly associated with metabolic abnormalities and healthcare costs than BMI[21]. A single WC measurement has been suggested to be used to identify individuals who should seek and be offered weight management[24]. We have used both BMI and WC measures to define total and central overweight and obesity in order to have a more complete overall picture of the problem in the Catalan population.

This study has shown that in Catalonia, in 2002–03, mean BMI in males was higher than in 1992–93, and that of females was lower (except for the youngest group); on the other hand, overall prevalence of BMI overweight and obesity were 43.7% and 16.6%; respectively in males and 30.1% and 15.2% respectively in females. When comparing these figures with those of the 2002 IOTF report for Spain (1998–2000), we observe that overweight was lower in Catalonia in both genders (in Spain 48% for males and 40% for females), while obesity was higher for Catalan males and females (in Spain 12% and 15%, respectively)[25]. Therefore, in terms of gender, this study shows that overweight and obesity are more prevalent in men (obesity was more prevalent in women 13 years ago, but male obesity has caught up and overcome the female prevalence). These findings are in agreement with other literature available from developed countries, which suggests that women hold a more negative attitude towards obesity than men and they are also more heavily influenced by the public negative view towards obesity, thus spending more time, effort and money on the ideal thinner shape[26].

Regarding WC overweight and obesity prevalences, this study has shown that in ENCAT 2002–03, mean WC was higher in males and females as compared to ENCAT 1992–93 (except for the female group aged 45–64 years). In men, overall WC overweight increased (from 21.7% in 1992–93 to 23.8% in 2002–03) as well as overall WC obesity (from 13.1% to 24.4%) increased. In women, overall WC overweight decreased (from 21.8% to 17.7%), while overall WC obesity increased (from 24.5% to 31.1%). In other words, our results on BMI and WC overweight and obesity suggest that Catalan men are getting bigger overall and also specifically around the waist, while Catalan women are getting thinner overall but with bigger waistlines. They also show that WC obesity is increasing more rapidly than BMI obesity and, while BMI obesity is more prevalent among men, WC obesity is more prevalent among women. These findings agree with those of several recent studies carried out in Northern Europe[21,27].

There are few studies that examine the possible relationship of SES and overweight and obesity prevalence, and even fewer for the actual distribution of its prevalence into the SES groups[21,26,28]. Although comparisons are not directly possible, there are three studies that show that obesity rates have been increasing for decades and are in line with our findings in that the prevalence of obesity is higher for the lower SES groups (two of these studies use education[29,30] and one uses income[28]) and for men. Data from the ENCAT 2002–03 survey showed an increasing trend in the prevalence of BMI obesity in all male SEL (using occupation) groups as compared to ENCAT 1992–93, whereas female BMI obesity prevalence only increased in the high SEL group (although not significantly). The analysis showed that SEL had no influence on male BMI overweight or obesity prevalence, and that it only had an influence on BMI overweight and obesity prevalence among the oldest females (45–64 years and 65–75-year-olds), showing an inverse relationship (this further stratification by age group is not shown in the results). Referring to WC, in the 10-year period, only female WC overweight and obesity changed due to SEL, overweight decreased (being highest in the lowest SEL but no inverse relationship was observed) and obesity increased (highest in the lowest SEL, showing an inverse relationship). These findings are in agreement with numerous studies carried out in developed countries by which, overall, the prevalence of obesity is higher in lower SEL groups[2,21,31]. In developing countries the problem has been shown to be more prevalent among the highest SEL groups, some showing the inverse relationship between overweight/obesity and household amenities in both genders and occupational level in men[32].

Studies within the Spanish population have shown that the prevalence of obesity is higher among women and increases with age, particularly in the least educated female subgroups[2,8], results that agree with the findings of the present study. The further stratification of each education level by age group (not shown in the results) revealed different prevalences from the overall male and female BMI obesity prevalences probably because the least educated people were mostly the older age groups with a higher obesity prevalence, which agrees with findings from the SEEDO'97 Study[2]. Regarding WC, we have shown that overweight basically increased in the male and female highest ELS groups, while obesity increased in all ELS groups, being highest in the lowest ELS one (inverse relationship) and most prevalent among the females of this group (reaching an alarming prevalence of 69.5%), and affecting more prominently the 45–64-year-olds (again probably because the least educated people were mostly the older age groups with a higher WC obesity prevalence – analysis not shown). These results coincide with those obtained in recent studies[12,27,33], in particular, a study carried out in Spain, which showed an even higher prevalence of WC obesity in non-educated elderly females (80.9%)[33].

With regard to the influence of the area of residence (population size) on excess body weight, in the 10-year period, significant differences were found for BMI overweight in both sexes and for female BMI obesity; the differences were also significant for WC male and female overweight and female WC obesity. Females living in the smallest communities showed a decrease in BMI and WC overweight. However, this decrease was probably at the expense of an increase in female WC obesity. Studies carried out on the Spanish population[2,34] disagree with our BMI findings by not showing significant differences on overweight and obesity when stratifying by population size, but no comparable results are available for WC prevalences.

Finally, SES has been found to be associated with dietary patterns and physical activity[26,31,35,36]. For example, showing more disadvantaged population groups generally have a poorer-quality diet (e.g. higher fat intake and lower vegetable consumption) than higher SES groups, which may partly explain the inverse association between SES and obesity demonstrated in some studies[26,35]. Other studies have evaluated how money expenditure on food can assist in the achievement of a healthy diet[26,37]. The inverse relationship between energy density and energy cost suggests that 'obesity-promoting' foods are simply those that offer the most dietary energy at the lowest cost. The relative cost has also been taken into account in the literature which increases even further the cost of the healthy diet for the low-income families[26]. The present study has not considered diet, physical activity, income (at least not directly), expenditure on food or food costs in its analysis (which was merely descriptive and far from suggesting causality due to the cross-sectional nature of the data); therefore, the authors recognise the need for a further and more robust analysis that involves all these lifestyle variables known to affect the relationship between prevalence of excess body weight and SES. In addition, self-reported occupation and education level may be over or under estimated. However, this probably has not significantly modified the classification of the participants into the three SES groups. Moreover, this study has not adjusted WC for BMI, which should be done due to the influence a high BMI can have on a high WC[21]. In spite of the mentioned limitations, we believe that our findings contribute to the evidence needed to guide public health policy makers in the design and implementation of preventive campaigns against the increasing trends of overweight and obesity, paying special attention to males and low SEL and education-level groups, and small population of residence size (for male overweight and female obesity).

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Authorship responsibilites: AGA was responsible for the statistical analysis, data interpretation and writing of the paper; LSM was director of the study and revised the paper providing expert advice on data interpretation and discussion of the paper; LRB was coordinator of the study and responsible of the databases and revised the paper providing expert advice on data interpretation; CC participated in the study concept and design; MF, RU, AP and LS revised the paper providing expert advice in its discussion.

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ANNEX IVb - Article:

Trends in the association between smoking history and general/central obesity in Catalonia (1992-2003), Spain

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Trends in the association between smoking history and general/central obesity in Catalonia (1992-2003), Spain

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Abstract

Trends in the relationship between smoking history and both general and central fatness in adults from a Mediterranean setting are shown. The ENCAT 1992-1993 and 2002-2003 surveys were used; 482 men and 589 women from 1992-1993 and 515 men and 613 women from 2002-2003, aged 25-60years. Measured anthropometry and self-reported data on smoking habits, diet, lifestyle and SES were collected. Sex-adjusted percentages were used to describe prevalence of overweight, obesity, Increased-Risk-for-metabolic-disease Waist Circumference (IR WC) and Substantially-Increased-Risk WC (SIR WC), (WHO criteria) among never-, former-, and current-smokers. Multivariate-adjusted associations were estimated using simple logistic regression. By 2002-2003, male prevalence of both joint overweight/obesity and IR/SIR WC had increased; former-smokers had the highest overweight (57.2%) and SIR WC (28.2%), but never-smokers had the highest obesity (19.3%) and current-smokers the highest IR WC (30.7%). Disparities in female rates across smoking groups were substantially diminished due to increased joint rates in former -and current-smokers, and lower joint rates in never-smokers; highest overweight (32.2%) and IR WC (21%) in former-smokers and highest obesity (16.5%) and SIR WC (33.2%) in never-smokers. After ten years, most associations had been strongly attenuated: only male current-heavy-smoking remained associated with IR/SIR WC (three-fold) and female current-moderate-smokers were 0.57 times less likely to have an IR/SIR WC ($p<0.10$). Although causality cannot be established, results suggest a positive association between heavy smoking and central fatness among men, but no association between former smoking and general/central fatness; findings strengthen arguments for promoting smoking cessation to reduce smoking- and obesity-associated morbidity and mortality.

Keywords: BMI; Cross-sectional; Obesity; Spain; Tobacco smoking; Waist circumference

Introduction

In developed countries, the most important modifiable factors recognised as responsible for excess mortality and morbidity at the population level are tobacco smoking and obesity [1-3]. Smoking cessation has been associated with increased risk of weight gain [4,5]. In addition, it has been suggested that current smoking — particularly of high intensity — may increase insulin resistance and may thus be associated with central fat accumulation [6], which could increase the risk of diabetes and metabolic syndrome and, hence, the risk of cardiovascular disease [7,8]. Thus in addition to more direct pathways, smoking may also contribute to morbidity and mortality indirectly through an influence on obesity, particularly as numerous studies suggest that central fatness is a more important determinant of disease risk than is generalized obesity [9-11]. Individuals with elevated waist circumference (WC), a marker of abdominal fat accumulation, appear to have higher risks of developing diabetes [12], hypertension [13] and CVD [14] than those with elevated BMI alone.

Although the relationship between overweight/obesity and smoking is receiving increasing attention [7,15-17], a greater pool of evidence is needed, especially on the relationships between central fatness and smoking. In particular, it is crucial to explore both the emerging evidence that central fatness and current heavy smoking may co-occur, and attenuation of the relationships between weight status and smoking cessation over the longer term. Moreover, given that the studies where there was not an increased risk of overweight or obesity associated with smoking were conducted fairly recently [5,6,18], it is important to assess whether and how the rising prevalence of obesity in the general population may influence relationships observed between smoking and body weight.

The aim of this paper is to contribute to the understanding of these issues by examining the relationships between past and current tobacco use and both BMI and WC in a Mediterranean area with high smoking [19] and obesity rates [20,21]. Our objectives are: 1) to examine 10-year prevalence trends in observed general/central fatness patterns among subjects of different smoking habits; 2) to examine the association between smoking and both general/central fatness after adjusting for possible confounders; and 3) to understand how these relationships change with temporal trends in the prevalence of both obesity and smoking.

Materials and methods

Conduction of the surveys

The Evaluation of the Nutritional Status of the Catalan Population (ENCAT) is a regional survey carried out every ten years by the Department of Health of the Catalan Government and co-ordinated by the FIN (formerly the CRENC). So far, two surveys have been conducted: the ENCAT 1992-1993 and the ENCAT 2002-2003. ENCAT's random sample population consisted of civilian non-institutionalized individuals aged 6 to 75, living in 82 Catalan municipalities of different sizes (ENCAT 1992-1993 with an N=2,757 and ENCAT 2002-2003 with an N=2,160). The sample was weighted to reflect the population distribution in the official census. The response rate for the first survey was 68.9% and for the second 66.0%. Further details on sampling have been described elsewhere [22-24].

Recruitment of each of the selected sample populations was carried out using the IDESCAT census [25]. Selected individuals who were going to be interviewed received an information letter from the Department of Health announcing the study and asking for their collaboration. When fieldwork started, the interviewer visited the home of the person selected and requested his/her participation; if the person could not be contacted (at least three attempts at different times in the day), the person was replaced with a substitute of the same age group and sex.

Study sample population

Data used in the current paper consisted of 1,242 individuals from the ENCAT 1992-1993 and of 1,223 individuals from the ENCAT 2002-2003 - all aged 25-60 years. However, analysis included all subjects aged 25-60 years with available data on anthropometric measures and smoking history, i.e. from ENCAT 1992-1993, a total of 1,071 subjects, 482 men (45.0% of the sample) and 589 women (55.0%),,and from ENCAT 2002-2003, a total of 1,128 subjects, 515 men (45.7%) and 613 women (54.3%). Mean age, the gender distribution, and level of education did not differ between the analysis sample and the full sample aged 25-60 years ($p>0.05$ for all three variables) in either of the surveys.

Data collection

All data were collected by trained dietician-interviewers using standardized questionnaires and anthropometric measurements (weight, height and waist circumference) during a home interview. Weight and height were measured with a portable spring scale and a metric tape (Kawer model). The individuals were measured in standardised conditions, wearing underwear and no shoes. Weight was measured in kilograms, scale measurement error 6100 g. Height was measured standing and head in the Frankfurt horizontal position, expressed in centimetres, instrumental measurement error 60.1 cm. Waist circumference (WC) was measured with a non-elastic metric tape halfway between the lower border of the ribs and the iliac crest on a horizontal plane; measurements were recorded to the nearest 0.1 cm.

In ENCAT 1992-1993, a first 24-hour dietary recall was conducted in a warm season – May/July - and a second one in a cold season - November/December. In 2002-2003, the 24-hour dietary recalls were conducted throughout the entire year; in both surveys the dietary recalls were conducted on different days of the week including weekend days. Food data was coded into groups and quantified by the interviewers and supervised by two dieticians. The food composition tables used were the Spanish Food Composition Tables of CESNID [24].

Variables

BMI (weight (kg)/height^2 (metres)) was used as an indicator of general excess in total body fat independent of height. WHO's standard cut-off points were used to define general overweight (BMI 25-<30 kg/m^2) and obesity (BMI $\geq$30 kg/m^2) [26]. Underweight (BMI<18.5 kg/m^2) individuals (0.2% of men and 1.9% of women in 1992-1993 and 0.4% of men and 2.3% of women in 2002-2003) were combined with normal weight (BMI 18.5-<25 kg/m^2) individuals, since separating these two groups had no meaningful effect on results (not shown).

WC provided an index of abdominal fatness, which has more recently been included in efforts to classify obesity, as the distribution of body fat has been found to be important and carrying it around the abdomen has been found to be especially unhealthy [27]. The recommended sex-specific cut-off points for risk of metabolic complications were used: WC >94 cm (men) and WC >80 cm (women) for increased-risk (hereafter “IR WC”), and 102 cm (men) and 88 cm (women) for substantially-increased-risk (hereafter “SIR WC”) [28].

Multivariate-adjusted associations between smoking history are reported for overweight and obesity combined (hereafter "overweight/obesity", as findings were generally similar for overweight and obesity when examined separately using multinomial logistic models, and the sample size for exploring obesity separately was limited given that very few smokers were obese (data not shown). Similarly, IR and SIR WC were combined in the multivariate models (hereafter IR/SIR WC), as findings were similar when these variables were examined separately (not shown).

Information on tobacco smoking was collected by self-report. Smoking history was defined as "never smoker", "former smoker" (had quit at the time of the interview but had smoked in the past for at least 6 months or longer) and “current smoker” (includes both daily and occasional smokers consuming <1 cigarette/day). Smoking intensity was defined as "light" (1-10 cig/d), "moderate" (11-20 cig/d) and "heavy" (>20 cig/d). Individuals smoking >20 cigarettes/day were considered as heavy smokers because this corresponds to the quantity of cigarettes contained in a standard pack in Western countries and other studies have also used this cut-off [29,30].

The covariates considered were: *sex*; *age*, defined as "20-40 years" and "41-60 years" (i.e. using the median age); *physical activity (PA) at work* –which was provided by questions adapted from the WHO physical activity “Countrywide Integrated Non-communicable Diseases Intervention” questionnaire [31] used in the ENCAT 1992–93 and ENCAT 2002–03 surveys- was defined as "sedentary", "light and moderate activity" and "active and very active" based on each subject's current employment, where sedentary occupations included those where most time is seated, light and moderate included standing occupations, and active or very active included manual occupations; *occupation social class* –for which the definition of Garcia-Alvarez et al. (2007)[20] was used, although slightly modified- was defined based on the subject's occupation as: "low" (including farm labourer and fishermen, manual unskilled and skilled workers, craftsmen/skilled industry workers, amenities and machinery guards), "medium" (including foremen, rest of administrative staff, commercial and technical staff, service sector, army, medium-level technicians, business owners without employees, agriculture skilled professional, support technician, administrative staff, writers and artists), "high" (including high-level technicians, self-employed professionals – dentists, lawyers etc, business owners with employees, directors/managers), and "other" (including the unemployed, housewives and the non-classifiable); *education level of the subject and of the family´s head member* (ELS and ELH) as defined in Garcia-Alvarez et al. (2007)[20]; *ethanol consumption*, classified as "level 1" (0-9.99 g/day – men and women), "level 2" (men: 10.00-29.99 g/day, women: 10.00-19.99 g/day), "level 3" (men: ≥30.00 g/day, women: ≥20.00 g/day) (1 standard unit of alcoholic beverage in Spain is equivalent to 10 g of ethanol [32]; *energy intake*, defined as "tertiles of intake (kcal/day)", *fruit and vegetable consumption*, defined according to recommendations [33-35] as "low" (<170g/day), "moderate" (170-400g/day)", "high" (>400g/day). Energy intake and fruit and vegetable consumption were obtained from the 24-hour recalls.

Statistical analysis

All analyses were performed with Intercooled Stata 8.0 for Windows (STATA Corporation, 98/95/NT. Texas, USA; 2002). In descriptive analyses, percentages were used to describe the prevalence of overweight, obesity, IR WC and SIR WC among men and women overall, and across smoking history strata; percentages were also used to describe the prevalence of smoking history by gender and age group. Weighted means with standard errors (SE) and proportions were used to describe the distribution of other variables across smoking history groups.

Multivariate-adjusted associations between smoking history variables and each obesity outcome (both for BMI and WC) were estimated using simple logistic regression. Separate models were fit for each survey, and for men and women; age-adjusted and multivariate adjusted results are presented. Models analyzed odds of "overweight/obesity", and "IR/SIR WC" among stratified current (light:<10/day), moderate:11-20/day) and heavy:>20/day) and former smokers vs. never smokers (the referent group). No data on smoking intensity was available for former smokers.

Variables included as confounders in the final multivariate models were: age, education level, occupation level, PA level at work, alcohol (ethanol) consumption, energy intake and fruit and vegetable consumption. Confounder selected included all variables that changed odds ratios of interest by >10% in at least some models. Within the analysis sample, sensitivity analyses were also carried out to assess whether missing values for covariates were influential, confirming that excluding subjects with missing values did not influence the main associations of interest (not shown). Final models excluded subjects with missing values for all covariates included. Results are presented as odds ratios (ORs) and 95% confidence intervals (CIs). Mantel-Haenzel test for trend was used to determine whether there was a dose-dependent relationship between smoking history/intensity and BMI and between smoking history/intensity and WC ($p<0.05$ as significance level). All prevalence estimates and ORs were weighted using the Catalan census population of 1991 and 2001 [36] respectively, accounting for the population gender and age group distribution.

Results

Prevalence and trends in general and central obesity

Levels of overweight/obesity were substantial, and consistently higher in men than in women (55.3% vs. 44.4% in 1993 and 64.7% vs. 42.2% in 2003, $p<0.05$); levels of IR/SIR WC, also substantial, were initially higher in women than in men (35.9% in men vs. 48.6% in women $p<0.05$) but very similar in the second survey (men 50.9% vs. women 49.1%, $p<0.05$) (Table 1).

Over time, there was a substantial increase in the prevalence of obesity (7%) as well as in SIR WC (11%) in men, though levels of overweight and IR WC were fairly stable. Among women, there was a substantial increase in the prevalence of SIR WC (7%), though overweight and obesity levels remained fairly stable and IR WC declined. Thus overall, among men, there were increases in overweight/obesity (55.3% and 64.7% in 1992-1993 and 2002-2003 respectively) and IR/SIR WC (35.9% and 50.9%), while among women levels of overweight/obesity (44.5% and 42.2%) and IR/SIR WC (48.6% and 49.1%) remained fairly stable, albeit with an increase in the prevalence of SIR WC (Table 1).

Prevalence and characteristics of never, former and current smokers

In 1992-1993, 53.6% of men and 30.8% of women reported being current smokers. Over time, as shown in Table 2, the prevalence of current smoking decreased substantially in men (by 13%), though only slightly in women (2%), while the percent of former smokers increased (by almost 4% in men and by 9% in women). The prevalence of heavy smoking (>20/day) declined from 10.9% to 8.2% in men, and from 3.2% to 2.1% in women (not shown). Table 2 also shows that, among males, both mean BMI and WC increased in all smoking history groups, with larger increases among never than former or current smokers (4.8 cm vs. 3.0 cm for WC). Among female never smokers, however, mean BMI and WC decreased over time, while both measures of obesity increased among former and current smokers. Moreover, among men in both surveys, current smokers had the highest percentages of low occupational social class, low levels of education, sedentary physical activity at work, low fruit and vegetable consumption and high ethanol consumption. However, among females, these percentages were highest in never smokers.

Shifts in the prevalence of general and central obesity by smoking history group

Figures 1 and 2 show prevalence rates of general and central obesity by smoking history. In 1992-1993, among men, former smokers had the highest prevalence of overweight, obesity, and both IR and SIR WC. By 2002-2003, however, substantial increases among never and current smokers led to levels of general and central obesity similar to those in former smokers. More specifically, in 2002-2003, while former smokers had the highest prevalence of overweight (57.2%) and SIR WC (28.2%), never smokers had the highest rates of obesity (19.3%) and current smokers had the highest level of IR WC (30.7%).

Fig. 1 Prevalence of BMI categories in male (top) and female (bottom) never smokers, former smokers and current smokers, by Survey. ENCAT 1992-1993 and 2002-2003

Fig. 2 Prevalence of WC categories in male (top) and female (bottom) never smokers, former smokers and current smokers, by Survey. ENCAT 1992-1993 and 2002-2003

In contrast to men, among women, in 1992-1993 the prevalence of overweight, obesity, IR WC and SIR WC was highest among never smokers. As among men, however, in 2002-2003 disparities in prevalence rates across smoking groups were substantially diminished as a consequence of increased levels in both former and current smokers, as well as lower levels in never smokers.

Associations between smoking history and general and central obesity: 1992-1993

Age- and multivariate-adjusted associations between smoking history and overweight/obesity and IR/SIR WC are presented in Table 3. In 1992-1993, the multivariate-adjusted analysis showed that male moderate and heavy smokers were 0.40 and 0.63 times less likely to be overweight/obese than never smokers, although the association was only significant ($p<0.05$) for moderate smokers. Neither former smoking nor current-light smoking was associated with general obesity among men. For central fatness, however, both male former and current-heavy smoking were associated with a more than two-fold increased odds of IR/SIR WC compared to never smoking ($p<0.05$).

In contrast to the null association among men, women who were current-light smokers were significantly less likely to be overweight/obese than never smokers (OR 0.42, CI 0.22-0.81). For central fatness, both former and current-light smokers had lesser odds of an IR/SIR WC than never smokers, with associations significant at the 10 and 5% level respectively, again contrary to the positive association between central fatness and former smoking observed in men.

Results of the Mantel-Haenszel test for trend (Table 3) show a significant trend ($p=0.007$) only in male BMI overweight/obesity-smoking OR; in females however, OR for both BMI overweight/obesity-smoking and IR/SIR WC-smoking show a significant trend ($p=0.000$ and $p=0.006$ respectively).

Associations between smoking history and general and central obesity: 2002-2003

In 2002-2003, when the prevalence rates of general and central obesity were notably higher, particularly in men, a rather different situation emerged, with most associations strongly attenuated compared to those observed in 1992-1993. Thus among men, current moderate and heavy smoking were no longer associated with general overweight/obesity, and former smoking was no longer associated with IR/SIR WC. However, current heavy smoking remained associated with IR/SIR WC, although the magnitude of the association was nearly two-fold rather than three-fold.

Associations were similarly attenuated towards the null among women in 2002-2003. Current light smoking was no longer associated with reduced odds of overweight/obesity or with reduced odds of IR/SIR WC, and former smoking was no longer associated with reduced odds of IR/SIR WC. However, current moderate smokers were 0.57 times less likely to have an IR/SIR WC as compared to never smokers, although the association was very weak ($p<0.10$).

Results of the Mantel-Haenszel test (Table 3) show a significant trend in female BMI overweight/obesity-smoking OR and IR/SIR WC-smoking OR ($P=0.046$ and $P=0.025$ respectively), but not in any of the male OR.

Discussion

The analysis of these two samples of adults from the region of Catalonia yielded very different results and may illustrate the trends in tobacco use and its body weight implications in a Mediterranean setting.

The 1992-1993 general overweight, obesity and excess central fatness prevalence rates were higher in male former smokers and female never smokers. Similar results showing lower BMI in current smokers have been reported by other studies [17, 37-42]. However, findings by John et al. (2005)[18] only agree with our female results, as they found lower overweight or obesity in female heavy smokers as compared to never smokers; nevertheless, our results from heavy smoking in women could not be properly analyzed because the sample size was too small. For males, they found higher proportions of overweight or obesity among moderate smokers as compared to never smokers.

Between 1992-1993 and 2002-2003, current smoking prevalence, initially more than 50%, declined substantially in men, though it remained fairly stable among women (30.8 and 28.8%). Other authors that studied the period 1982-1998 in the region also found decreasing smoking prevalence trends among Catalan men, but increasing trends among Catalan women and young adults of both sexes, concluding that tobacco smoking rates were stable [19]. Using data from 2005, the WHO reported similar percentages of tobacco use among Spanish adults, which ranged between 28.6-36.5% [43].

In addition, levels of overweight, obesity, IR and SIR WC were substantial in 1992-1993, but there were nonetheless substantial increases over time, particularly in obesity and SIR WC. According to the ENRICA study [44], in Catalonia, by 2010, male general obesity prevalence had reached a 23.7% (an increase of 8 percentage points if compared to ENCAT 2002-2003) and that of female a 21.2% (an increase of 7 percentage points when compared to ENCAT 2002-2003). The increases in obesity and SIR WC observed in ENCAT were highest among male never smokers, but were also substantial among current female smokers, with smaller increases in former smokers.

Moreover, associations between current smoking intensity and general obesity, adjusted for confounders such as subject's age, energy intake, physical activity at work, education level and occupation, were initially strongly negative in men for moderate and heavy smoking, and in women for light smoking. By 2002-2003, null associations were observed, indicating that current smokers were no longer leaner than never smokers.

With some exceptions indicating no association [6], the majority of studies on this topic have found negative associations between current smoking—especially moderate and heavy smoking—and general obesity [3,5,18,40,42]. No previous studies have looked at changes in associations coinciding with shifts in the prevalence of obesity and smoking over time. These shifts in results suggest that the increased overweight and obesity among current smokers diminish disparities in prevalence vs. never smokers.

Mechanisms for a possible causal relationship between current smoking and a lower BMI may include the increased metabolic rate induced by nicotine [6,7,45], the decreased metabolic efficiency or the decreased caloric absorption (reduction of appetite) [7,46,47] or the lower consumption of desserts –choosing to smoke after lunch instead- that some authors have observed among men (but not in women) [46]; an increased total energy expenditure involving the stimulation of the sympathetic nervous system [45], although weaker among obese subjects [48] and also depending on physical activity and fitness degree [49,50].

In contrast, despite negative associations between smoking and general overweight/obesity, there were strong positive associations between current heavy smoking—but not moderate or light smoking—and central obesity in men. These associations were only slightly attenuated in 2002-2003: this was the most persistent association observed. Among women, moderate smokers and the small number of heavy smokers had similar levels of IR/SIR WC as did never smokers, although current light smoking was initially associated with reduced odds of IR/SIR WC; by 2002-2003, however, after multivariate adjustment, female light smokers had similar levels of IR/SIR WC to those of never smokers, and moderate smokers, unexpectedly, had lower levels ($p<0.10$).

Our finding of a positive association for heavy smoking in men is again in line with results reported by Travier et al. (2009)[42] and Clair et al. (2011)[6], who found heavy smoking to be positively associated with elevated WC, though in those studies this was observed in both sexes. Clair et al. however, did observe a positive association between moderate smoking and elevated WC in men. On the other hand, the negative association between moderate smoking and central obesity in women is in line with Travier et al.'s (2009)[42] findings, which observed a lower elevated WC in female current smokers of the average number of cigarettes, but did not observe this in men. Again, changes in associations at different points in time have not been reported previously, but results in men suggest that disparities between current smokers and never smokers are diminished as levels of central obesity rise among the never smokers.

A possible mechanism for a greater WC among smokers is, for instance, the higher fasting plasma cortisol concentrations seen in smokers as compared to non-smokers, which are strongly associated with visceral adipose tissue (VAT) [51,52], in turn strongly associated with WC [53]; higher cortisol concentrations could be a consequence of the stimulation of sympathetic nervous system activity that is induced by smoking [15,54]. In addition, sex hormones may be involved. In women, low concentrations of estrogens and an excess of androgens such as testosterone - typically seen after menopause [55] - has been associated with VAT accumulation [55-57]. In men, VAT increases when testosterone concentration decreases [58], and testosterone administration in middle-aged men reduces VAT by increasing lipolysis [59]; in addition, smoking may reduce testosterone concentrations [58-60]. However, in the case of heavy smokers, the mentioned increase in metabolism induced by nicotine might be outweighed by the metabolic effects of nicotine that favour abdominal fat accumulation and the smokers propensity for unhealthy lifestyle habits, thus causing an direct relationship for heavy smokers and WC as compared to light smokers [6,7].

In 1992-1993, age-adjusted associations between former smoking and general overweight/obesity were weakly positive in men but strongly negative in women as compared to never smokers; after multivariate adjustment for confounders such as subject's age, energy intake, physical activity at work, education level and occupation, both the positive and negative associations seen in men and women respectively were attenuated. However, it is important to note that associations with former smoking were strongly diminished over time, as the prevalence of obesity increased more among never and current smokers. Our results are in line with those by John et al. (2005)[18], who found that former smokers did not reveal more overweight or obesity than never smokers, suggesting that a short-term increase in body weight after smoking cessation does not become critical in public health terms when never smokers are taken as the reference group. Other authors, however, have reported different results for male former smokers indicating that they weigh more than never smokers [17,38,42]. Mechanisms for weight gain among male former smokers might include higher energy intake, decreased resting metabolic rate and physical activity and possibly changes in adipose tissue metabolism [61,62]. Moreover, it has been suggested that more female than male quitters might develop decisions or psychological strategies that are strong enough to curb weight gain [18,63].

Associations between former smoking and central obesity: in 1992-1993 were strongly positive in men as compared to never smokers, persisting even more strongly positive after multivariate adjustment for age, energy intake, subject's education level and fruit and vegetable consumption; these results have been found previously in men [5]. In women, however, age-adjusted associations were strongly negative, persisting at a lower significance level (10%) after multivariate adjustment. These results for both men and women are in line with those of Travier et al.'s (2009)[42], although they analysed the association in former smokers of the average time since quitting. In contrast, Pisinger and Jorgensen (2007)[17] observed that female quitters had a higher increase in WC than men. Nevertheless, our results show that by 2002-2003, when levels of central obesity had increased especially in the never and current smokers, no association between former smoking and central obesity was observed.

Moreover, it is important that results have been derived from multivariate-adjusted analyses with the intention to eliminate as much as possible the effect of confounders such as physical activity, energy intake or alcohol consumption on the relationship between smoking and general/central fatness. In this sense, Chiolero et al. (2008)[7] suggested that, heavy smokers tend to have greater body weight than light smokers or non-smokers because heavy smokers are more likely to adopt behaviours favouring weight gain (e.g. low physical activity, sedentary life style, unhealthy diet, and high alcohol intake) than are light smokers or non-smokers. It is noteworthy that we found very little disparity in age-adjusted vs. multivariate-adjusted results, and the list of variables included in the adjustment did not explain persistent positive associations between current heavy smoking and central obesity (in men).

The reasons for the observed gender disparities are unclear. Previous studies reporting gender disparities are also found in the literature [6,40-42,64]. However, other studies that have considered the effects of confounding factors such as alcohol and food intake, physical activity, and education still showed similar findings between sexes [3,65,66]. It has been argued that the sex difference could be explained by a stronger antiestrogenic effect of nicotine in women as compared to men [67]. Heterogeneity in the results could be caused by differences in sample sizes, because smaller studies are less likely to detect modest effects, variation in reporting smoking variables and other important confounders, and age structure of the population [41]. In our study, the very small number of women who reported themselves to be heavy smokers may be limiting the ability to examine associations between current heavy smoking and central obesity and compare them with those observed in men.

We recognise the following study limitations: the cross-sectional nature of the surveys, which does not allow us to establish any definitive temporal association between smoking and general/central adiposity; relying on self-reported measures of smoking habits; using surrogate markers for fat distribution; the missing data on anthropometry (outcomes) and smoking history (exposure) variables, although, no significant differences in terms of age, education and socio-economic status (occupation) were observed when the sample of individuals with missing data on outcome and exposure variables was compared with the sample that had all data.

Regarding confounders, some important factors observed in other studies to have had a large/meaningful impact on the smoking-general/central fatness relationship and, which were available for our analyses, include age, energy intake, physical activity/exercise, alcohol consumption, education level [5,18,42] and socioeconomic status [5,68,69], although they had a minimal impact on our results and in other studies [6]. Failing to adjust for potential confounders described in other studies such as residence [5], weight cycling [37], location of work/urbanization [70,71], menopausal status

[28,42], parity – associated with increases in WC [28], marital status [70], is unlikely to have had a large impact; but we cannot totally rule out the effect of confounding caused by factors that we have not considered.

The major strengths of the present study include: that it uses measured anthropometry; that it is based on two general population samples of relatively large total size, which provide a rather good number of explanatory factors (potential confounders) and detailed information on current smoking intensity; but most importantly, it is based on two methodologically very similar samples that are 10-years apart, which allows for comparison and trends identification.

We conclude that although causality cannot be established, results suggest a positive association between heavy smoking and central fatness among men, but no association between former smoking and general/central fatness; findings strengthen arguments for promoting smoking cessation to reduce morbidity and mortality associated with both smoking and obesity.

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Conflict of interest Author CC is an employee of the Catalonia's Public Health Agency (http://www20.gencat.cat/portal/site/salut/menuitem.81a4919118f3026913a90f10b0c0e1a0/?vgnextoid=afc125837e73f310VgnVCM2000009b0c1e0aRCRD&vgnextchannel=afc125837e73f310VgnVCM2000009b0c1e0aRCRD (former General Directorate of Public Health), funders of the two ENCAT surveys. However, her affiliation has not influenced either the design of the surveys, their implementation or the writing of the present article. The other authors have no conflicts of interest to declare.

Ethical approval Before starting the fieldwork, the two Evaluations of the Nutritional Status of the Catalan Population (surveys ENCAT 1992-93 and ENCAT 2002-03) were ethically approved by the Catalan Department of Health. The two surveys were coordinated by the Fundación para la Investigación Nutricional (FIN) ("Nutritional Research Foundation") of the University of Barcelona Science Park. Written informed consent was obtained from all participants before joining the ENCAT surveys. All data were recorded manually i.e. pen-and-paper. The data were made anonymous when recorded electronically i.e. the respondents' contact details were not entered into the survey database. Instead, the FIN assigned ID numbers to each respondent and used these assigned ID numbers in the analysis process.

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Table 1. Prevalence of overweight[a], obesity[b], IR WC[c] and SIR WC[d], by gender and survey.

	Men		Women	
	ENCAT 1992-93 (n=502)	**ENCAT 2002-03 (n=595)**	**ENCAT 1992-93 (n=602)**	**ENCAT 2002-03 (n=590)**
Overweight/obesity[e]	55.3%	64.7%	44.5%	42.2%
Overweight	46.8%	49.2%	31.0%	28.4%
Obesity	8.5%	15.5%	13.5%	13.8%
IR/SIR WC[f]	35.9%	50.9%	48.6%	49.1%
IR WC	24.0%	28.1%	24.8%	18.4%
SIR WC	11.9%	22.8%	23.8%	30.7%

[a]Overweight= BMI 25-<30 kg/m^2; [b]Obesity= BMI ≥30 kg/m^2; [c]IR WC= Increased-risk of metabolic complications (i.e. WC >94 cm for men and WC >80 cm for women); [d]SIR WC= Substantially-increased-risk of metabolic complications (i.e. WC= >102 cm for men, and WC>88 cm for women); [e]Overweight/obesity = overweight plus obese subjects; [f]IR/SIRWC = subjects with IR WC plus subjects with SIR WC.

Table 2. Male and female characteristics by survey and cigarette smoking history.

Characteristics	Cigarette smoking history					
	Never		**Former**		**Current**	
ENCAT	**1992-93**	**2002-03**	**1992-93**	**2002-03**	**1992-93**	**2002-03**
MEN	26.1%	35.9%	20.3%	23.9%	53.6 %	40.2%
Age (years)	40.6 (0.98)	40.1 (0.75)	44.9 (1.08)	45.3 (0.84)	40.0 (0.69)	38.7 (0.66)
BMI (kg/m^2)	25.6 (0.28)	26.6 (0.29)	26.5 (0.33)	26.9 (0.29)	25.2 (0.21)	26.1 (0.26)
WC (cm)	89.5 (0.82)	94.3 (0.85)	92.5 (1.05)	95.5 (0.91)	89.8 (0.65)	92.8 (0.77)
Percent low social class[a]	25.8%	35.4%	22.2%	25.3%	52.0%	39.4%
Percent low education level[b] (< 6 years)	24.4%	29.5%	31.3%	24.8%	44.3%	45.7%
Percent low HH education level[c] (< 6 years)	27.8%	35.8%	25.1%	21.1%	45.2%	43.2%
Percent sedentary occupational physical activity	33.0%	37.8%	23.3%	25.5%	43.8%	36.7%
Total energy intake (kcal/d)	2209.2 (38.8)	2173.2 (26.8)	2121.2 (48.7)	2112.2 (32.6)	2219.9 (33.9)	2139.5 (29.6)
Percent low fruit & vegetable consumption (<170g/d)	21.8%	31.9%	11.2%	16.4%	67.1%	51.7%
Percent high ethanol consumption (level 3)	29.9%	14.3%	5.0%	42.4%	65.1%	43.3%
WOMEN	56.9%	49.5%	12.3%	21.3%	30.8%	28.8%
Age (years)	45.1 (0.63)	42.8 (0.63)	36.5 (0.86)	41.4 (0.81)	35.2 (0.70)	38.0 (0.71)
BMI (kg/m^2)	26.6 (0.31)	25.2 (0.25)	23.6 (0.42)	25.1 (0.43)	23.5 (0.27)	24.5 (0.35)
WC (cm)	83.5 (0.78)	82.4 (0.71)	76.5 (1.19)	82.1 (1.12)	76.8 (0.70)	80.6 (1.01)
Percent low social class[a]	68.1%	54.3%	6.3%	19.7%	25.6%	25.9%
Percent low education level[b] (< 6 years)	76.5%	64.9%	6.9%	14.3%	16.6%	20.8%
Percent low HH education level[c] (< 6 years)	65.8%	60.6%	5.1%	15.7%	29.1%	23.7%
Percent sedentary occupational physical activity	48.4%	46.6%	13.9%	20.9%	37.7%	32.5%
Total energy intake (kcal/d)	1606.7 (20.4)	1661.5 (19.2)	1627.8 (33.2)	1671.7 (30.0)	1684.9 (23.5)	1663.9 (25.9)
Percent low fruit & vegetable consumption (<170g/d)	45.9%	40.5%	10.9%	16.0%	43.3%	43.5%
Percent high ethanol consumption (level 3)	52.3%	47.1%	18.8%	9.4%	29.0%	43.5%

Values are proportions or means (SE) as shown.

[a]Low occupational social class defined based on the household head's occupation being manual or unskilled workers, as well as farmers or fishermen.

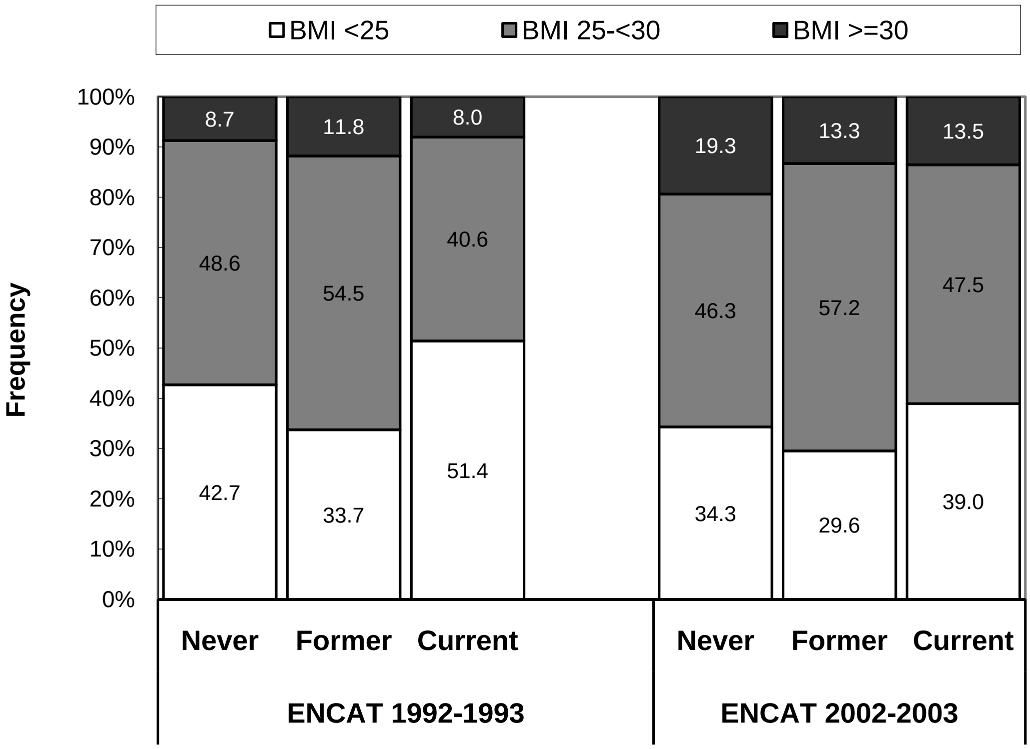
[b]Low education level defined as< 6 years of schooling for each individual.

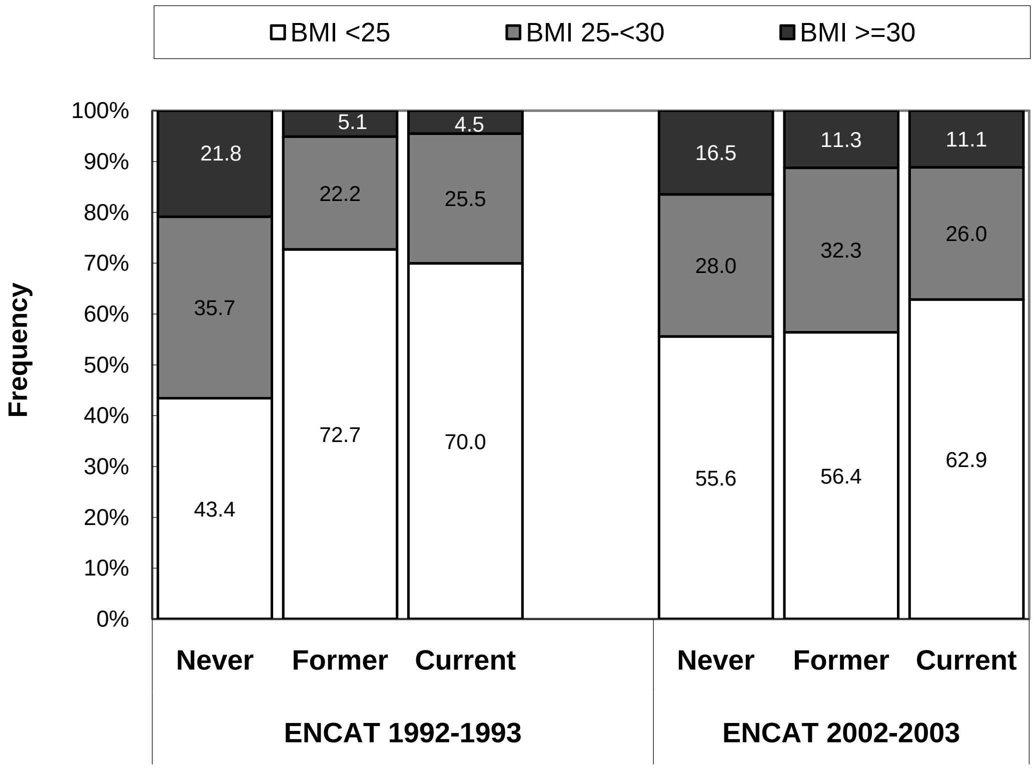
[c]Low household head (HH) education level defined as< 6 years of schooling.

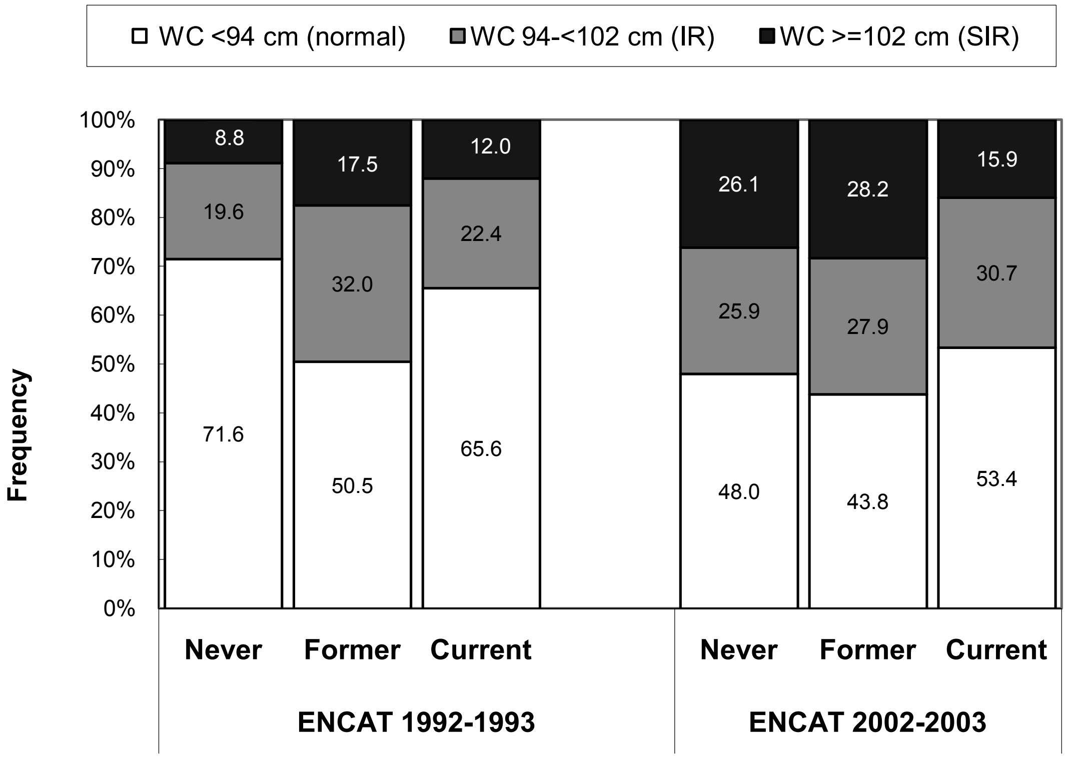
Table 3. Associations between smoking history and overweight/obesity and increased-risk/substantially-increased-risk WC (IR/SIR WC).

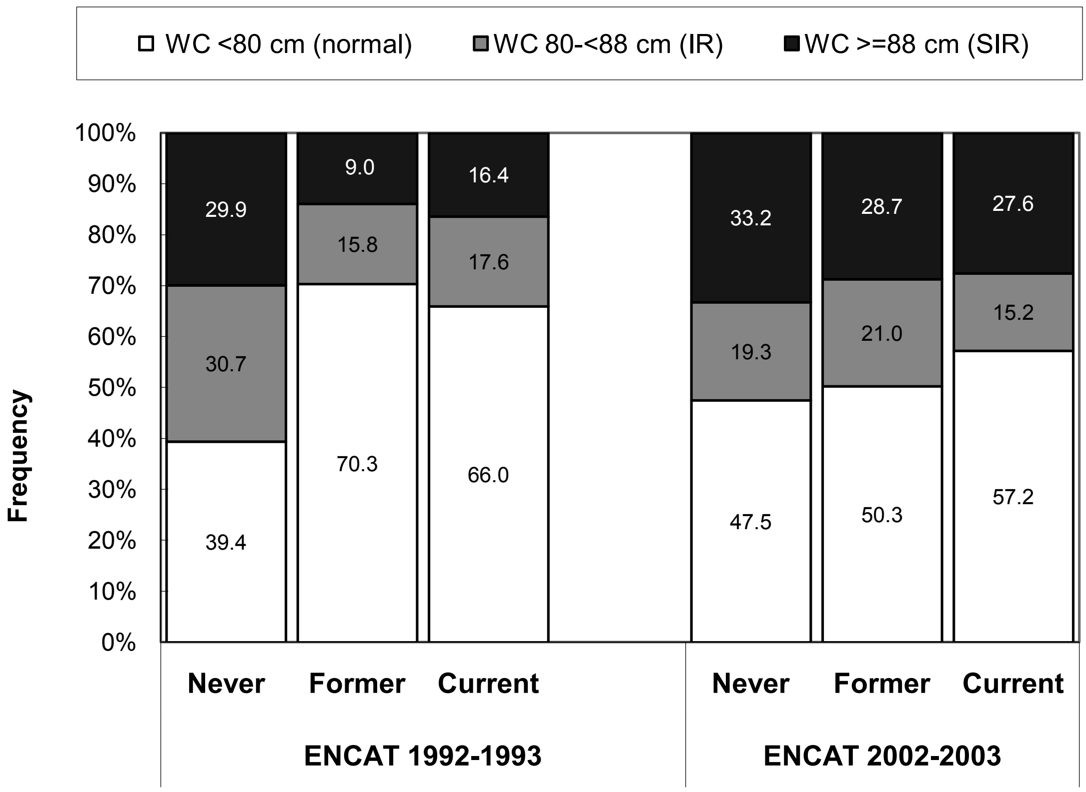
Smoking history	Overweight/obesity (BMI $\geq$25 kg/m^2)				IR/SIR WC (WC>94 cm in men, WC>80 cm in women)			
	ENCAT 1992-93		ENCAT 2002-03		ENCAT 1992-93		ENCAT 2002-03	
	n	OR (95% CI)	n	OR (95% CI)	n	OR (95% CI)	n	OR (95% CI)
AGE-ADJUSTED ASSOCIATIONS								
Men	469		508		468		507	
Never (ref)	74	1.0	121	1.0	37	1.0	95	1.0
Former	68	1.23 (0.67-2.25)	88	0.98 (0.58-1.65)	50	**2.03*(1.08-3.81)**	70	0.94 (0.57-1.56)
Current light (<=10cig/day)	48	1.23 (0.65-2.31)	40	0.72 (0.39-1.32)	22	0.94 (0.47-1.89)	29	0.67 (0.36-1.24)
Current moderate (11-20cig/day)	46	**0.47*(0.26-0.83)**	46	0.81 (0.45-1.46)	34	1.13 (0.60-2.10)	31	0.67 (0.38-1.17)
Current heavy (>20cig/day)	24	0.61 (0.30-1.21)	31	1.22 (0.56-2.66)	24	**2.51*(1.22-5.14)**	29	**1.82‡(0.87-3.83)**
Women	579		611		574		610	
Never (ref)	187	1.0	151	1.0	195	1.0	174	1.0
Former	20	**0.51*(0.27-0.98)**	58	1.02 (0.65-1.61)	22	**0.48*(0.25-0.91)**	66	0.94 (0.59-1.48)
Current light (<=10cig/day)	24	**0.48*(0.26-0.89)**	34	1.01 (0.60-1.69)	23	**0.42*(0.22-0.78)**	41	0.95 (0.57-1.56)
Current moderate (11-20cig/day)	24	0.85 (0.42-1.75)	21	0.65 (0.35-1.22)	30	1.06 (0.54-2.12)	23	**0.53*(0.29-0.97)**
Current heavy (>20cig/day)	8	1.09 (0.40-2.99)	6	**1.13*(2.18-4.33)**	6	0.84 (0.29-2.46)	7	1.09 (0.26-4.60)
MULTIVARIATE-ADJUSTED ASSOCIATIONS								
Men	443		503		442		502	
Never (ref)		1.0		1.0		1.0		1.0
Former		1.33 (0.69-2.54)[a]		0.97 (0.57-1.67)[c]		**2.37*(1.19-4.69)[b]**		1.01 (0.61-1.68)[d]
Current light (<=10cig/day)		1.00 (0.52-1.93)[a]		0.73 (0.39-1.36)[c]		0.93 (0.46-1.92)[b]		0.71 (0.37-1.35)[d]
Current moderate (11-20cig/day)		**0.40*(0.22-0.75)[a]**		0.75 (0.41-1.36)[c]		1.12 (0.59-2.22)[b]		0.58 (0.32-1.04)[d]
Current heavy (>20cig/day)		0.63 (0.31-1.29)[a]		1.11 (0.50-2.51)[c]		**2.73*(1.21-6.16)[b]**		**1.98‡(0.91-4.31)**[d]
MH# test for trend		0.007		0.481		0.904		0.986
Women	528		591		523		590	
Never (ref)		1.0		1.0		1.0		1.0
Former		0.71 (0.37-1.38)[a]		1.27 (0.78-2.05)[c]		**0.56‡(0.29-1.09)[b]**		1.14 (0.71-1.83)[d]
Current light (<=10cig/day)		**0.42*(0.22-0.81)[a]**		1.20 (0.67-2.13)[c]		**0.39*(0.20-0.77)[b]**		1.15 (0.68-1.93)[d]
Current moderate (11-20cig/day)		0.76 (0.36-1.60)[a]		0.71 (0.37-1.36)[c]		1.00 (0.49-2.05)[b]		**0.57‡(0.30-1.09)[d]**

OR= odds ratio, CI = confidence interval. BMI= body mass index; overweight= BMI 25-<30 kg/m^2; obesity= BMI$\geq$30 kg/m^2; overweight/obesity = overweight plus obese subjects. WC= waist circumference; IR WC/SIR WC = subjects with IR WC plus subjects with SIR WC; IR WC= Increased-risk of metabolic complications (i.e. WC>94 cm for men, WC>80 cm for women); SIR WC= Substantially-increased-risk (i.e. WC>102 cm for men, WC>88 cm for women); *p<0.05; ‡p<0.10. #MH=Mantel-Haenszel. a. Adjusted for age, energy intake, physical activity level at work, ELS and SES-occupation. b. Adjusted for age, energy intake, ELS and fruit and vegetable consumption. c. Adjusted for age, energy intake, ELH, ELS, SES-occupation, fruit and vegetable consumption and ethanol consumption. d. Adjusted for age, energy intake, ELS, SES-occupation and ethanol consumption.


BMI <25
BMI 25-<30
BMI >=30
Frequency
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
8.7
48.6
42.7
11.8
54.5
33.7
8.0
40.6
51.4
19.3
46.3
34.3
13.3
57.2
29.6
13.5
47.5
39.0
Never
Former
Current
Never
Former
Current
ENCAT 1992-1993
ENCAT 2002-2003


BMI <25
BMI 25-<30
BMI >=30
Frequency
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
21.8
35.7
43.4
5.1
22.2
72.7
4.5
25.5
70.0
16.5
28.0
55.6
11.3
32.3
56.4
11.1
26.0
62.9
Never
Former
Current
Never
Former
Current
ENCAT 1992-1993
ENCAT 2002-2003


WC <94 cm (normal)
WC 94-<102 cm (IR)
WC >=102 cm (SIR)
Frequency
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
8.8
19.6
71.6
17.5
32.0
50.5
12.0
22.4
65.6
26.1
25.9
48.0
28.2
27.9
43.8
15.9
30.7
53.4
Never
Former
Current
Never
Former
Current
ENCAT 1992-1993
ENCAT 2002-2003


WC <80 cm (normal)
WC 80-<88 cm (IR)
WC >=88 cm (SIR)
Frequency
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
29.9
30.7
39.4
9.0
15.8
70.3
16.4
17.6
66.0
33.2
19.3
47.5
28.7
21.0
50.3
27.6
15.2
57.2
Never
Former
Current
Never
Former
Current
ENCAT 1992-1993
ENCAT 2002-2003

ANNEX IVc - Article:

Usage of plant food supplements across six European countries: findings from the PlantLIBRA Consumer Survey

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Usage of Plant Food Supplements across Six European Countries: Findings from the PlantLIBRA Consumer Survey

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Abstract

Background: The popularity of botanical products is on the rise in Europe, with consumers using them to complement their diets or to maintain health, and products are taken in many different forms (e.g. teas, juices, herbal medicinal products, plant food supplements (PFS)). However there is a scarcity of data on the usage of such products at European level.

Objective: To provide an overview of the characteristics and usage patterns of PFS consumers in six European countries.

Design: Data on PFS usage were collected in a cross-sectional, retrospective survey of PFS consumers using a bespoke frequency of PFS usage questionnaire.

Subjects/setting: A total sample of 2359 adult PFS consumers from Finland, Germany, Italy, Romania, Spain and the United Kingdom.

Data analyses: Descriptive analyses were conducted, with all data stratified by gender, age, and country. Absolute frequencies, percentages and 95% confidence intervals are reported.

Results: Overall, an estimated 18.8% of screened survey respondents used at least one PFS. Characteristics of PFS consumers included being older, well-educated, never having smoked and self-reporting health status as ''good or very good''. Across countries, 491 different botanicals were identified in the PFS products used, with *Ginkgo biloba* (Ginkgo), *Oenothera biennis* (Evening primrose) and *Cynara scolymus* (Artichoke) being most frequently reported; the most popular dose forms were capsules and pills/tablets. Most consumers used one product and half of all users took single-botanical products. Some results varied across countries.

Conclusions: The PlantLIBRA consumer survey is unique in reporting on usage patterns of PFS consumers in six European countries. The survey highlights the complexity of measuring the intake of such products, particularly at pan-European level. Incorporating measures of the intake of botanicals in national dietary surveys would provide much-needed data for comprehensive risk and benefit assessments at the European level.

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Competing Interests: Simone de Klein and Eva Melanie Meissner are employees of PhytoLab GmbH & Co. KG, Vestenbergsgreuth, Germany: PhytoLab GmbH & Co. KG is an independent, accredited (in accordance with DIN EN 17025) and officially recognized service laboratory (in accordance with § 14 AMG [German Drug Law], which is also GMP-certified. Analysis, development, quality control and regulatory affairs of herbal products (herbal medicinal products, food, food supplements and cosmetics) are its areas of work. The company consists of a modern laboratory and service centre, with about 180 employees. PhytoLab GmbH & Co. KG does not produce or sell own products. Please, see also www.phytolab.com. Within the PlantLIBRA EC project, PhytoLab GmbH & Co. KG is Beneficiary number 13 of the PlantLIBRA Consortium, as well as a partner of what constitutes "Work Package 1 (WP1)" (www.plantlibra.eu), having performed the same tasks and activities as the other 5 partners involved in the WP1 PlantLIBRA PFS Consumer Survey (i.e. the institutions included as the affiliations of the submitted article). Their key contributions to PlantLIBRA are as follows: analysis of contaminants, analysis of secondary compounds, safety/efficacy assessment, and regulatory affairs. Within WP1, their key contribution to the Survey work was their expertise in PFS botanical composition (together with the University of Milan), which became essential during the survey data reviewing process". In addition, the authors, in particular Angela Marculescu, Transilvania University of Brasov, Romania, declare the following funding received from the PFS industry in the last 3 years: 1) SC Hofigal Export-Import SA sponsored the 2012 conference BIOATLAS in Brasov, covering costs of products for advertising and travel and accommodation costs of Prof. Gilles Bedoux from Franta (University Bretagne Sud), to attend this conference; 2) Some other Romanian companies such as Hofigal, DaciaPlant, Fares Orastie, Paradisul Verde were sponsors of the Romanian Society of Etnofarmacology, where Angela Marculescu is the President. However, neither of these companies has influenced either the design of the survey, its implementation or the writing of the present article. Moreover, the organization of the BIOATLAS conference had no relationship with the PlantLIBRA Project, and neither did the participation of the sponsored speaker. There are no patents, products in development or marketed products to declare. The above does not alter the authors' adherence to all the PLoS ONE policies on sharing data and materials.

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Introduction

Botanicals and their derivatives/preparations are used throughout Europe for health purposes, with increased usage in the general population as well as among specific subgroups encompassing children and pregnant women or those suffering from diseases such as cancer among others [1–4]. Botanicals are used in many different types of products, including foods, (teas and juices), food supplements such as plant food supplements (PFS), herbal medicinal products (HMP), homeopathic products, cosmetics, biocides etc [5]. These different product categories are regulated by specific legislation, depending on the intended use of the product.

The European Union (EU) Directive on Food Supplements (2002/46/EC) defines dietary supplements (which include PFS) as [6]:

"…foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles and other similar forms of liquids and powders designed to be taken in measured small quantities".

The marketing of a product as a PFS however, depends on national legislation, which differs widely across Member States. Countries vary in the extent to which products are regulated, as well as in the process of regulatory control. Some countries have regulated the use of botanicals in detail (including negative and positive lists), some apply specific conditions of use, (including maximum usage levels or warnings for the consumer), and in others less specific requirements exist. An added complexity lies in the application of the basic European "principle of mutual recognition", whereby any product that is lawfully marketed in one Member State can be sold in all 27 Member States [5].

Moreover, the same botanical may be used as a food supplement and as a medicinal product, depending on the intended use of the product and both food supplements and medicinal products often share the same form of presentation (powders, pills or tablets). Hence the legal status of products differs from one country to another, resulting in a complex market environment. This so-called borderline issue between PFS and HMP is a major obstacle to the marketing of PFS in the European Union [5].

Plant food supplement usage data at EU level are scarce with reports providing PFS market data as opposed to data reported directly by the consumer [7]. Surveys on the intake of botanicals have been conducted primarily in the context of the intake of dietary supplements in general [8] or as part of surveys of complementary and alternative medicine (CAM) therapies [9], and issues such as the legal distinction between HMP and PFS have not been taken into account. A recent systematic review evaluating the demographic characteristics and health status factors associated with CAM use reported that the majority of population based consumption studies had been conducted in the USA (64% of the 110 identified studies), and of these, 13% were in Europe, with the majority carried out in Scandinavia (7%) and the United Kingdom (5%) [4]. Studies have been limited by the heterogeneity of definitions used, study designs and objectives making it difficult to compare results and to extrapolate

Table 1. Validation study results.

Variable	Concordance[a]	Milan		Las Palmas de Gran Canaria	
		n	%	n	%
Product used	Yes	47	95.9	48	100.0
	No	2	4.1	0	0.0
Dose form (pills, capsules, etc)	Yes	45	91.8	47	97.9
	No	4	8.2	1	2.1
Doses per day	Yes	45	91.8	38	79.2
	No	4	8.2	10	20.8

[a]Concordance between both methods: the PFS usage questionnaire and the 6-month usage diary.
doi:10.1371/journal.pone.0092265.t001

Table 2. Distribution of screened individuals, PFS consumers interviewed and prevalence sample by country and gender.

			Finland	Germany	Italy	Romania	Spain	United Kingdom	Total
Total contacts (n)	Total individuals screened for the survey	Males	1405	1031	907	795	811	830	5779
		Females	1379	1028	1044	827	932	794	6004
	Total PFS consumers interviewed accepted	Males	193	197	187	199	174	191	1141
		Females	208	201	191	201	228	189	1218
Prevalence sample: systematically selected sample 1st three months of the Fieldwork (n)	Individuals screened	Males	486	564	439	502	551	454	2996
		Females	519	571	547	501	648	563	3349
	PFS consumers among Individuals screened	Males	33	90	99	95	55	65	437
		Females	71	111	156	124	133	144	739
PFS consumption prevalence (weighted) (%)			9.6	16.9	22.7	17.6	18.0	19.1	18.8

doi:10.1371/journal.pone.0092265.t002

conclusions. The ambiguity of categories such as "natural medicine", "herbal remedies" or "herbal medicine" and what constitutes "dietary supplements" makes it nearly impossible to attain reliable estimates of the prevalence of PFS usage in Europe, with only limited data available at national levels [9–11] but not at the European level.

A study by the European Advisory Services (EAS) on "The use of substances with nutritional or physiological effect other than vitamins and minerals in food supplements" [7], provided information on European market and regulation data, and highlighted the need for obtaining PFS usage data in order to plan, monitor and evaluate national and European policies, as in other regions of the world. One such example is the United States of America, where the Alternative Health/CAM supplement of the National Health Interview Survey (NHIS) has been collecting data on botanical dietary supplements for some years now [12–14].

The European Food Safety Authority (EFSA) has recognised the lack of data in the sector and has published a number of reports addressing related issues, namely the recommendations for reporting the use of supplements and medicines by adults in any pan-European dietary survey or project [15], and the "Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health", aimed to help with the safety assessment of botanicals and botanical preparations intended for use as food supplements [16].

The purpose of this paper is to describe the type and frequency of PFS usage reported in a retrospective survey of consumers in six European countries; in addition we present the most frequently used botanical ingredients in these products. We also highlight the issues associated with measuring usage of PFS in European populations and make recommendations for future research.

Materials and Methods

Ethics statement

Before initiating the fieldwork, approval for the conduct of the survey was obtained from four ethics committees: the Bioethics Commission of the University of Barcelona, Spain; the Ethics Committee of the University of Milano, Italy; the Ethical Committee of the Faculty of Medicine - Transilvania University of Brasov, Romania; and the Coordinating Ethics Committee, Hospital District of Helsinki and Uusimaa, Finland. Approval of the survey by these four ethics committees required submitting all survey material to their members for evaluation. No ethical approval for the survey was needed in Germany and the United Kingdom.

To ensure harmonisation and standardisation of the fieldwork and data collection across countries, a market research organization, *European Fieldwork Group* (EFG) was subcontracted to implement the survey. The survey was conducted by EFG in strict accordance with the ICC/ESOMAR Code on Market and Social Research. In all countries, informed consent was obtained verbally from all respondents after reading the survey information sheet. All data were recorded manually i.e. pen-and-paper. Recruitment of survey participants occurred in the selected cities in each country. Approximately the first 1000 individuals per country were systematically selected for screening i.e. intercepting 1 in every 5 individuals passing by to ask him/her the initial screening questions; subsequent screening selection was performed on a convenience basis i.e. intercepting individuals in places where consumers were likely to be found, such as herbal shops, pharmacies etc. Eligible respondents who agreed to participate were given an appointment at their home/workplace to complete

Table 3. PlantLIBRA's PFS consumer survey – socio-demographic sample characteristics, overall and by country.

Characteristics	Categories	All countries		Finland		Germany		Italy		Romania		Spain		United Kingdom	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Gender	Male	1141	48.4 (46.4–50.4)	193	48.1 (43.2–53.0)	197	49.5 (44.6–54.4)	187	49.5 (44.4–54.5)	199	49.8 (44.8–54.7)	174	43.3 (38.4–48.1)	191	50.3 (45.2–55.3)
	Female	1218	51.6 (49.6–53.7)	208	51.9 (47.0–56.8)	201	50.5 (45.6–55.4)	191	50.5 (45.5–55.6)	201	50.3 (45.3–55.2)	228	56.7 (51.9–61.6)	189	49.7 (44.7–54.8)
Age	18–29 years	418	17.7 (16.2–19.3)	63	15.7 (12.1–19.3)	77	19.4 (15.5–23.2)	84	22.2 (18.0–26.4)	122	30.5 (26.0–35.0)	38	9.5 (6.6–12.3)	34	9.0 (6.1–11.8)
	30–39 years	445	18.9 (17.3–20.4)	65	16.2 (12.6–19.8)	57	14.3 (10.9–17.8)	88	23.3 (19.0-27.6)	65	16.3 (12.6–20.0)	101	25.1 (20.9–29.4)	69	18.2 (14.3–22.0)
	40–49 years	460	19.5 (17.9–21.1)	64	16.0 (12.4–19.6)	82	20.6 (16.6–24.6)	63	16.7 (12.9–20.4)	46	11.5 (8.4–14.6)	88	21.9 (17.8–25.9)	117	30.8 (26.1–35.4)
	50–59 years	441	18.7 (17.1–20.3)	105	26.2 (21.9–30.5)	80	20.1 (16.2–24.0)	49	13.0 (9.6–16.4)	67	16.8 (13.1–20.4)	76	18.9 (15.1–22.7)	64	16.8 (13.1–20.6)
	≥60 years	595	25.2 (23.5–27.0)	104	25.9 (21.6–30.2)	102	25.6 (21.3–29.9)	94	24.9 (20.5–29.2)	100	25.0 (20.8–29.3)	99	24.6 (20.4–28.8)	96	25.3 (20.9–29.6)
Education	Low	249	10.6 (9.3–11.8)	47	11.7 (8.6–14.9)	3	0.8 (0.0–1.6)	72	19.1 (15.1–23.0)	35	8.8 (6.0–11.5)	92	22.9 (18.8–27.0)	0	–
	Medium	1549	65.7 (63.6–67.6)	237	59.1 (54.3–63.9)	329	82.7 (78.9–86.4)	222	58.7 (53.8–63.7)	190	47.5 (42.6–52.4)	256	63.7 (59.0–68.4)	315	82.9 (79.1–86.7)
	High	561	23.8 (22.1–25.5)	117	29.2 (24.7–33.6)	66	16.6 (12.9–20.2)	84	22.2 (18.0–26.4)	175	43.8 (38.9–48.6)	54	13.4 (10.1–16.8)	65	17.1 (13.3–20.9)
Current employment status	Employed	1357	57.5 (55.5–59.5)	204	50.9 (46.0–55.8)	240	60.3 (55.5–65.1)	221	58.5 (53.5–63.4)	249	62.3 (57.5–67.0)	244	60.7 (55.9–65.5)	199	52.4 (47.3–57.4)
	Other groups [a]	1002	42.5 (40.9–44.5)	197	49.1 (44.2–54.0)	158	39.7 (34.9–44.5)	157	41.5 (36.6–46.5)	151	37.8 (33.0–42.5)	181	39.3 (34.5–44.1)	181	47.6 (42.6–52.7)

[a]Other groups: Unemployed; Housework; Student; Retired; Disabled; and Other.

doi:10.1371/journal.pone.0092265.t003

Table 4. PlantLIBRA's PFS consumer survey – health-related lifestyle sample characteristics, overall and by country.

Characteristics	Categories	All countries		Finland		Germany		Italy		Romania		Spain		United Kingdom	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Regular use of non-PFS FS[ab]	No	1536	65.1 (63.2–67.0)	83	20.7 (16.7–24.7)	251	63.1 (58.3–67.8)	311	82.3 (78.4–86.1)	274	68.5 (63.9–73.1)	312	77.6 (73.5–81.7)	305	80.3 (76.3–84.3)
	Yes	767	32.5 (30.6–34.4)	306	76.3 (72.1–80.5)	122	30.7 (26.1–35.2)	63	16.7 (12.9–20.4)	112	28.0 (23.6–32.4)	89	22.1 (18.1–26.2)	75	19.7 (15.7–23.7)
	Not sure	56	2.4 (1.8–3.0)	12	3.0 (1.3–4.7)	25	6.3 (3.9–8.7)	4	1.1 (0.1–2.1)	14	3.5 (1.7–5.3)	1	0.3 (0.0–0.7)	0	–
Smoking habit	Never smoker	1100	46.6 (44.6–48.6)	182	45.4 (40.5–50.3)	183	46.0 (41.1–50.9)	181	47.9 (42.8–52.9)	214	53.5 (48.6–58.4)	177	44.0 (39.2–48.9)	163	42.9 (37.9–47.9)
	Former smoker	544	23.1 (21.4–24.8)	129	32.2 (27.6–36.8)	81	20.4 (16.4–24.3)	85	22.5 (18.3–26.7)	57	14.3 (10.8–17.7)	94	23.4 (19.2–27.5)	98	25.8 (21.4–30.2)
	Current smoker	715	30.3 (28.5–32.2)	90	22.4 (18.4–26.5)	134	33.7 (29.0–38.3)	112	29.6 (25.0–34.2)	129	32.3 (27.7–36.8)	131	32.6 (28.0–37.2)	119	31.3 (26.7–36.0)
Self-reported health status	Very good	353	15.0 (13.5–16.4)	81	20.2 (16.3–24.1)	49	12.3 (9.1–15.5)	22	5.8 (3.5–8.2)	80	20.0 (16.1–23.9)	49	12.2 (9.0–15.4)	72	19.0 (15.0–22.9)
	Good	1427	60.5 (58.5–62.5)	225	56.1 (51.3–61.0)	220	55.3 (50.4–60.2)	243	64.3 (59.5–69.1)	245	61.3 (56.5–66.0)	258	64.2 (59.5–68.9)	236	62.1 (57.2–67.0)
	Neither bad nor good	496	21.0 (19.4–22.7)	77	19.2 (15.3–23.1)	111	27.9 (23.5–32.3)	111	29.4 (24.8–34.0)	73	18.3 (14.5–22.0)	81	20.2 (16.2–24.1)	43	11.3 (8.1–14.5)
	Bad	70	3.0 (2.3–3.7)	16	4.0 (2.1–5.9)	18	4.5 (2.5–6.6)	2	0.5 (0.0–1.3)	2	0.5 (0.0–1.2)	14	3.5 (1.7–5.3)	18	4.7 (2.6–6.9)
	Very bad	13	0.6 (0.3–0.9)	2	0.5 (0.0 – 1.2)	0	–	0	–	0	–	0	–	11	2.9 (1.2–4.6)
CAM[c] usage	Yes	947	40.1 (38.2–42.1)	223	55.6 (50.7–60.5)	204	51.3 (46.3–56.2)	96	25.4 (21.0–29.8)	77	19.3 (15.4–23.1)	319	79.4 (75.4–83.3)	28	7.4 (4.7–10.0)
	No	1412	59.9 (57.9–61.8)	178	44.4 (39.5–49.3)	194	48.7 (43.8–53.7)	282	74.6 (70.2–79.0)	323	80.8 (76.9–84.6)	83	20.7 (16.7–24.6)	352	92.6 (90.0–95.3)
Alcohol consumption	0-<1 times/day	1398	59.3 (57.3–61.3)	281	70.1 (65.6–74.6)	245	61.6 (56.8–66.3)	116	30.7 (26.0–35.3)	232	58.0 (53.2–62.8)	291	72.4 (68.0–76.8)	233	61.3 (56.4–66.2)
	≥1 times/day	296	12.6 (11.2–13.9)	13	3.2 (1.5–5.0)	27	6.8 (4.3–9.3)	156	41.3 (36.3–46.2)	9	2.3 (0.8–3.7)	46	11.4 (8.3–14.6)	45	11.8 (8.6–15.1)
	Not sure	614	26.0 (24.3–27.8)	107	26.7 (22.4–31.0)	126	31.7 (27.1–36.2)	106	28.0 (23.5–32.6)	159	39.8 (35.0–44.6)	65	16.2 (12.6–19.8)	102	26.8 (22.4–31.3)
BMI[d] categories	Underweight	69	2.9 (2.4–3.6)	9	2.2 (0.8–3.7)	4	1.0 (0.0–2.0)	12	3.2 (1.4–4.9)	20	5.0 (2.9–7.1)	6	1.5 (.3–2.7)	18	4.7 (2.6–6.9)
	Normal weight	1116	47.3 (45.3–49.3)	188	46.9 (42.0–51.8)	198	49.7 (44.8–54.7)	246	65.1 (60.3–69.9)	184	46.0 (41.1–50.9)	169	42.0 (37.2–46.9)	131	34.5 (29.7–39.3)
	Overweight	818	34.7 (32.8–36.6)	147	36.7 (31.9–41.4)	159	40.0 (35.1–44.8)	98	25.9 (21.5–30.4)	142	35.5 (30.8–40.2)	155	38.6 (33.8–43.3)	117	30.8 (26.1–35.4)
	Obesity	356	15.1 (13.7–16.5)	57	14.2 (10.8–17.6)	37	9.3 (6.4–12.2)	22	5.8 (3.5–8.2)	54	13.5 (10.2–16.9)	72	17.9 (14.2–21.7)	114	30.0 (25.4–34.6)
Physical activity[e]	Low	436	18.5 (16.9–20.1)	53	13.2 (9.9–16.5)	87	21.9 (17.8–25.9)	141	37.3 (32.4–42.2)	5	1.3 (0.2–2.3)	43	10.7 (7.7–13.7)	107	28.2 (23.6–32.7)
	Moderate	909	38.5 (36.6–40.5)	156	38.9 (34.1–43.7)	139	34.9 (30.2–39.6)	191	50.5 (45.5–55.6)	53	13.3 (9.9–16.6)	234	58.2 (53.4–63.0)	136	35.8 (31.0–40.6)
	High	1012	42.9 (40.9–44.9)	192	47.9 (43.0–52.8)	171	43.0 (38.1–47.8)	45	11.9 (8.6–15.2)	342	85.5 (82.1–89.0)	125	31.1 (26.6–35.6)	137	36.1 (31.2–40.9)

[a]***Question asked***: Other than PLANT FOOD SUPPLEMENT, have you taken any of the following supplements on a regular basis in the last 12 months? (mark all that apply). ***Possible responses***: Vitamins (A, B, D, E, etc.); Minerals (eg. potassium, calcium); Amino acids; Enzymes (eg. lactase); Prebiotics (eg. oligosaccharides, fibre); Probiotics (eg. bifidobacteria, yeasts); Fatty acids (eg. fish oil); Other.
[b]FS = Food supplements.
[c]CAM = Complementary and Alternative Medicine, including: Acupuncturist; Chiropractor; Homeopath; Herbalist; Massage therapist; Traditional/faith healer; Reflexologist; Recognised treatment i.e. not "alternative"; Esoteric treatment; and "Cannot be classified".
[d]BMI = Body Mass Index; WHO categories [18].
[e]IPAQ categories [19].
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Table 5. PlantLIBRA's PFS consumer survey – PFS usage patterns, per product used by a respondent, overall and by gender and age group.

	Total (n = 2874)		Gender				Age group			
			Male (n = 1358)		Female (n = 1516)		18–59 years (n = 2131)		≥60 years (n = 743)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
I took it whenever/sporadically	568	19.8 (18.3–21.2)	280	20.6 (18.5–22.8)	288	19.0 (17.0–21.0)	437	20.5 (18.8–22.2)	131	17.6 (14.9–20.4)
I take it periodically, during those times only	1072	37.3 (35.5–39.1)	533	39.3 (36.7–41.9)	539	35.6 (33.1–38.0)	827	38.8 (36.7–40.9)	245	33.0 (29.6–36.46)
I took it when I had a flare up/worsening of condition	638	22.2 (20.7–23.7)	278	20.5 (18.3–22.6)	360	23.8 (21.6–25.9)	451	21.2 (19.4–22.9)	187	25.2 (22.1–28.3)
Other reason	512	17.8 (16.4–19.2)	224	16.5 (14.5–18.5)	288	19.0 (17.0–21.0)	353	16.6 (15.0–18.1)	159	21.4 (18.5–24.4)
Not sure	84	2.9 (2.3–3.5)	43	3.2 (2.2–4.1)	41	2.7 (1.9–3.5)	63	3.0 (2.2–3.7)	21	2.8 (1.6–4.0)

Questions asked. During the last 12 months, in what months have you taken this supplement? (mark all that apply). ***Possible responses***: Jan, Feb, Mar, Apr, May, June, July, Aug, Sep, Oct, Nov, Dec, All year round; Why did you decide to take this supplement in the months stated? (one answer only). ***Possible responses***: I took it whenever/sporadically; I take it periodically, during those times only; When I had a flare up/worsening of condition; Other reason; Not sure.

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the main survey. The appointments of those willing to participate were later reconfirmed by phone.

The data were made anonymous when recorded electronically i.e. the respondents' contact details were not entered into the survey database. Instead, the market research organization assigned ID numbers to each respondent and provided PlantLIBRA partners only the database with the assigned ID numbers.

Definition of plant food supplements in the PlantLIBRA PFS consumer survey

Although there is a legal definition of Food Supplements (EU Directive (2002/46/EC) [6] under which PFS reside, for the purposes of this research it was necessary to develop a specific definition of PFS whose main characteristic is that they contain botanical preparations as ingredients for food supplementation.

Botanical preparations are obtained by subjecting botanicals (plants, algae, fungi or lichens) to treatments such as comminution, extraction, distillation, squeezing, fractionation, purification, concentration or fermentation. These include extracts, essential oils, expressed juices, powders, etc.

Botanical preparations can be considered as *nutrients* or *other substances*. Thus, the definition of PFS for the survey was as follows: PFS are "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of botanical preparations that have nutritional or physiological effect, alone or in combination with vitamins, minerals and other substances which are not plant-based. PFS are marketed in dose form, such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities".

Products that did not meet this definition, such as herbal remedies and other medicinal products based on botanicals, and those that did not meet the PFS definition in terms of dosage, such as herbal teas or juices, were excluded.

Sample population and PFS consumer definition

A cross-sectional, 12-month retrospective survey was conducted in 24 cities in six European countries -Finland, Germany, Italy, Romania, Spain and the United Kingdom. An estimated sample size of 2000 screened individuals per country was calculated in order to obtain a final sample of approximately 400 consumers per country (total N = 2400 approximately). Per country, gender and age group quotas were set as follows: 300 adults (18 to 59 years) and 100 older adults (60-and-over years), with 30–50% male and 50–70% female. All individuals were screened by means of a brief questionnaire which recorded PFS usage in the preceding 12 months. Individuals were considered eligible for inclusion if they were over 18 years old and met either of the following specified criteria, intended to capture the different usage patterns of PFS consumers:

1) They had taken at least 1 PFS in the last 12 months, in an appropriate dose form at a minimum frequency of either:

   a) 1 daily dose for at least 2 consecutive or non-consecutive weeks, or
   b) 1 or more doses per week for at least 3 consecutive weeks or
   c) 1 or more doses per week for at least 4 consecutive or non-consecutive weeks

2) They had taken 2 or more different PFS, in an appropriate dose form, at a minimum frequency of 1 or more doses per

Table 6. PlantLIBRA's PFS consumer survey – PFS usage patterns, per product used by a respondent, overall and by country.

	Finland (n = 665)		Germany (n = 446)		Italy (n = 417)		Romania (n = 464)		Spain (n = 465)		United Kingdom (n = 417)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
I took it whenever/sporadically	83	12.5 (10.0–15.0)	102	22.9 (19.0–26.8)	73	17.5 (13.9–21.2)	60	12.9 (9.9–16.0)	105	22.6 (18.8–26.4)	145	34.8 (30.2–39.4)
I take it periodically, during those times only	307	46.2 (42.4–50.0)	226	50.7 (46.0–55.3)	172	41.3 (36.5–46.0)	194	41.8 (37.3–46.3)	68	14.6 (11.4–17.8)	105	25.2 (21.0–29.4)
I took it when I had a flare up/worsening of condition	126	19.0 (16.0–21.9)	89	20.0 (16.2–23.7)	128	30.7 (26.3–35.1)	117	25.2 (21.3–29.2)	75	16.1 (12.8–19.5)	103	24.7 (20.6–28.8)
Other reason	140	21.1 (18.0–24.2)	26	5.8 (3.7–8.0)	32	7.7 (5.1–10.2)	51	11.0 (8.1–13.8)	214	46.0 (41.5–50.6)	49	11.8 (8.7–14.9)
Not sure	9	1.4 (0.5–2.2)	3	0.7 (0.0–1.4)	12	2.9 (1.3–4.5)	42	9.1 (6.4–11.7)	3	0.7 (0.0–1.4)	15	3.6 (1.8–5.4)

Questions asked. During the last 12 months, in what months have you taken this supplement? (mark all that apply) ***Possible responses***: Jan, Feb, Mar, Apr, May, June, July, Aug, Sep, Oct, Nov, Dec, All year round; Why did you decide to take this supplement in the months stated? (one answer only) ***Possible responses***: I took it whenever/sporadically; I take it periodically, during those times only; When I had a flare up/worsening of condition; Other reason; Not sure.

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week, with the sum of the usage period of the 2 or more products being equal to at least 4 weeks.

Instruments and variables

A short screening questionnaire was used to identify consumers who met the survey inclusion criteria; it consisted of six questions which allowed interviewers to identify eligible consumers, based on the product(s) used, the frequency and duration of use and the dose form. Eligible consumers subsequently completed a more detailed questionnaire on their PFS usage in the preceding 12 months, providing details of product/plant names, dosage forms, frequency of use, reasons for use, adverse effects, places and patterns of purchase and information sources on products. These questions were asked for each of up to a maximum of 5 different PFS used. In addition, respondents were asked to provide socio-demographic data including age, gender, level of education and employment status, as well as self-reported height and weight and further health-related lifestyle information.

Survey administration and data collection

Fieldwork and data collection for the cross-sectional survey were conducted by the international market research company EFG, from May 2011 to September 2012. The duration of the fieldwork ensured that any seasonal variability in usage of products was captured. The survey protocols and instruments -training material, information sheet, informed consent, screening and usage questionnaires-, were initially developed in English by consensus amongst the research team, and subsequently translated into the respective languages in each of the survey countries. Pilot interviews were conducted in each participating country to assess the comprehension of the questions and to determine the time required to complete the survey.

In each participating country, trained interviewers systematically screened approximately 1000 individuals during the first three months of the survey, which allowed the estimation of the prevalence rate. Subsequently, screening and recruitment were conducted on a convenience basis. The recruited eligible consumers were interviewed face-to-face and the more detailed PFS usage questionnaire completed.

Data preparation and statistical analysis

All data from the completed surveys were entered into the statistical package SPSS for Windows v. 18 (IBM Corporation, Somers, NY, USA), which was also used for data analysis.

Following review of the completed interviews by the research team in each country, a database with botanical composition data for all PFS products reported was compiled for each country and then merged into a single database. Potential product duplicates between countries were not removed. Each product was coded for its botanical ingredients in scientific, English and local names and botanicals were coded after removing duplicates between countries. Additionally, each product was categorised as a single- or multi-botanical product. To indicate the certainty of the matching of products, a series of numerical codes were used, based on those used in the National Health and Nutrition Examination Survey 2005–2006 [17]. Values ranged from 1–5, where "1" indicated an exact match, "2" a probable match, "3" a reasonable match, "4" a default match and "5" no match. Only products with certainty values 1 to 4 have been included in the analyses.

Respondent data were recorded in a separate database. A number of variables were created and/or recoded to facilitate reporting and analysis, including: 1) "education level", defined as low, medium, and high; 2) "BMI", which was calculated from self-reported weight

Table 7. PlantLIBRA's PFS consumer survey – Characteristics of PFS reported by respondents.

	Total	Finland	Germany	Italy	Romania	Spain	United Kingdom
Number of products	1288	213	190	289	196	284	116
Number of botanicals	491	196	191	222	219	218	47
Number of manufacturers	449	69	99	106	61	97	17
Maximum number of ingredients per product	46	23	46	20	39	30	8

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and height, and for which WHO criteria [18] were used to categorise individuals as underweight (BMI<18.5 kg/m^2), normal weight (BMI 18.5-<25 kg/m^2), overweight (BMI 25-<30 kg/m^2) and obese (BMI ≥30 kg/m^2); 3) "physical activity", calculated using the short version of the IPAQ [19] and defined as low, moderate or high.

Absolute frequencies and percentages for each of the variable categories were used to describe the qualitative nominal/ordinal and discrete quantitative survey data. In turn, all data have been stratified by gender, age range and country - also using absolute frequencies and percentages and 95% confidence intervals. When describing the association between two qualitative variables (nominal or ordinal), contingency tables were used. The continuous quantitative variables (e.g. BMI, alcohol) were recoded into categorical variables.

It is important to note that when reporting the main results of the survey, the unit of analysis varies depending on the variables used, i.e. for certain variables the unit is an individual respondent, however, given the potential intake of multiple supplements by one respondent, the unit of analysis may change to the supplement level. Furthermore, all results presented in the tables represent the analysis of raw data as opposed to data weighted by the population size. Data were not weighted because of the study methodology selected, whereby all country samples were very similar in size and included only PFS consumers.

Validation study

In order to validate the PFS usage questionnaire, a validation study was conducted in which the data collected using the survey instrument were compared with a 30 to 180-day diary (used as the gold standard). The study was conducted in two of the PlantLIBRA consumer survey cities: Las Palmas de Gran Canaria (Spain) and Milan (Italy), where 48 and 49 consumers respectively were recruited using convenience sampling. The PFS usage questionnaire was completed by the respondents at the beginning and at the end of the 6-month period of the validation; during this time the consumers also completed the usage diary. Data from the last questionnaire and the diary were compared for concordance, and results are shown in Table 1, indicating a good agreement for product consumed, dose form and doses per day.

Results

Characteristics of the PFS consumer sample

A final sample of 2359 consumers (those eligible and willing to participate) was recruited from 11783 screened individuals (Table 2). Due to different legal frameworks (different distribution of botanicals in food supplements and medicinal products), more individuals had to be screened in Finland in order to recruit the required 400 consumers. Table 2 also shows the sample used for the estimation of the usage prevalence rate. The estimated weighted overall PFS usage prevalence rate was 18.8% and per-country rates were as follows: Finland 9.6%, Germany 16.9%, Italy 22.7%, Romania 17.6%, Spain 18.0% and the United Kingdom 19.1%.

Survey respondents were recruited to fixed quotas for age and gender, which were achieved, with some differences within countries (Table 3). In Finland the proportion of adults aged 50–59 years was significantly higher (26.2%), whilst the opposite was true in Italy, where consumers in that age group constituted only 13.0% of adults. Romania had a significantly higher number of consumers in the youngest age group (30.5%), in contrast to Spain and the United Kingdom, where this age group represented only 9.5% and 9.0% of adult consumers, respectively. A significantly higher proportion of female consumers were recruited in Spain (56.7%) and in the United Kingdom marginally more males were recruited (50.3%). Across all countries, more than half of the participants (57.5%) were employed (Table 3), with the percentages slightly lower in Finland (50.9%) and in the United Kingdom (52.4%). The majority of participating consumers were educated to medium level (Table 3).

Respondents were asked a number of questions regarding health-related lifestyle factors (Table 4). Less than half of the consumers had never smoked (46.6%), less than one quarter were ex-smokers (23.1%) and less than one third were current smokers (30.3%).

More than half of the total respondents (59.3%) had not consumed alcohol or had consumed it less than once daily; more than a tenth (12.6%) reported daily alcohol consumption.

The proportion of overweight and obese people in the survey was 49.8% (Table 4). Some significant differences in levels of physical activity were noted between countries. High levels of activity were reported by 85.5% of Romanian respondents compared to a value of 42.9% across all countries.

Most of the respondents (65.1%) reported not being regular consumers of food supplements other than PFS in the preceding 12 months, except for Finland (Table 4). The proportion of non-consumers varied from 20.7% in Finland to more than 80% in the United Kingdom and Italy. By contrast, in Finland 76.3% of the individuals were regular consumers of food supplements.

Over half of all respondents (59.5%) reported not having used CAM therapies/treatments in the past year. This is particularly the case in Italy (74.6%), Romania (80.8%) and the United Kingdom (92.6%).

Three quarters of consumers reported their health status as very good or good (75.5%), while 3.6% reported it as bad or very bad and 21.0% as neither bad nor good (Table 4).

Between countries, more consumers reported their health status as very good or good in Romania (81.3%) and in the United Kingdom (81.1%) than in other countries; though conversely the highest proportion reporting their health status as bad or very bad was also in the United Kingdom (7.6%).

Table 8. PlantLIBRA's PFS consumer survey – number and type of products taken, overall distribution and by gender and age group.

		Total		Gender				Age group			
		(n = 2359)		Male (n = 1141)		Female (n = 1218)		18–59 years (n = 1764)		≥60 years (n = 595)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Number of products taken	1 product	1975	83.7 (82.2–85.2)	980	85.9 (83.9–87.9)	995	81.7 (79.5–83.9)	1496	84.8 (83.1–86.5)	479	80.5 (77.3–83.7)
	2 products	289	12.3 (10.9–13.6)	123	10.8 (9.0–12.6)	166	13.6 (11.7–15.6)	196	11.1 (9.6–12.6)	93	15.6 (12.7–18.6)
	>2 products	95	4.0 (3.2–4.8)	38	3.3 (2.3–4.4)	57	4.7 (3.5–5.9)	72	4.1 (3.2–5.0)	23	3.9 (2.3–5.4)
Product type	1 single-botanical	1214	51.5 (49.5–53.5)	606	53.1 (50.2–56.0)	608	49.9 (47.1–52.7)	900	51.0 (48.7–53.4)	314	52.8 (48.8–56.8)
	1 multi -botanical	761	32.3 (30.4–34.2)	374	32.8 (30.1–35.5)	387	31.8 (29.2–34.4)	596	33.8 (31.6–36.0)	165	27.7 (24.1–31.3)
	2 or more single-botanical	104	4.4 (3.6–5.2)	45	3.9 (2.8–5.1)	59	4.8 (3.6–6.1)	72	4.1 (3.2–5.0)	32	5.4 (3.6–7.2)
	2 or more single- and multi-botanical	280	11.9 (10.6–13.2)	116	10.2 (8.4–11.9)	164	13.5 (11.6–15.4)	196	11.1 (9.6–12.6)	84	14.1 (11.3–16.9)

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PFS usage patterns

Overall, products are most often taken "periodically" (37.3%) with respondents also reporting using PFS when experiencing a "flare up or worsening of a condition" (22.2%) (Table 5). Products are also used on a more "sporadic basis" (19.8%) and on "other non-specified occasions" (17.8%). Both men and women reported taking products on a periodic basis (39.3%, 35.6%) and this was also true for both age groups (Table 5). Periodic use was reported significantly more often in Finland (46.2%), Germany (50.7%), Italy (41.3%) and Romania (41.8%), but in Spain, "another reason" was most reported (46.0%) and in the United Kingdom, sporadic use (34.8%) was significantly higher than any other reason as to when products were used (Table 6).

PFS products used

Respondents reported a total of 1288 products across the six countries. At individual country level, the highest numbers of different PFS were used in Italy (289) and Spain (284); in the United Kingdom, the number of different PFS was approximately half that of the other countries (Table 7). The number of different botanical ingredients was 491, with the maximum number of different botanicals contained in a single product being 46 and present in a German product. The United Kingdom differed from the other countries as the products reported contained a lower number of botanical ingredients (maximum 8).

In terms of the number of products used, 83.7% of all consumers reported taking one product in the preceding 12 months, with 12.3% taking two products and 4.0% using more than two products (Table 8). Generally this pattern was similar for both men and women and across the age groups, although those over 60 did report a significantly higher use of two or more products than those under 60 (19.5% vs. 15.2%) (Table 8). At country level (Table 9), some significant differences were noted: in Finland, the percentage of consumers using two or more products was significantly higher than in all other countries (40.2%).

Overall 51.5% of consumers used a single-botanical product and 32.3% used one multi-botanical product (Table 8). There were no significant differences between males and females in this usage pattern, but consumers aged over 60 used less multi-botanical products than those aged 18–59 (27.7% and 33.8% respectively) (Table 8). Overall, fewer consumers reported using two or more single-botanical products (4.4%) and two or more single- and multi-botanical products (11.9%) (Table 8).

There were some significant differences across countries in the type of products consumed (Table 9). In the six countries, the values for single-botanical products range from 84.5% (the United Kingdom) to 20.5% (Finland). Usage of multi-botanical products was reported in all countries, with the lowest proportion (7.1%) reported in the United Kingdom (Table 9). The use of two or more single-botanical products was low in all countries as was the usage of two or more single- and multi-botanical products. Finland was an exception to the latter, with 38.2% of respondents taking multiple products (Table 9).

The most common dose forms used (Table 10) are capsules (38.3%) and pills/tablets/lozenges (36.8%). No significant difference was observed in relation to gender or age (Table 10). Across the six countries (Table 11), solid forms are generally most popular, although capsules were used less frequently in Romania (17.7%). Liquid forms were less common in the United Kingdom (8.2%) and Germany (9.9%), but more common in Finland (26.2%) and Italy (26.4%) (Table 11).

Table 9. PlantLIBRA's PFS consumer survey – number and type of products taken, by country.

		Finland (n = 401)		Germany (n = 398)		Italy (n = 378)		Romania (n = 400)		Spain (n = 402)		United Kingdom (n = 380)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Number of products taken	1 product	240	59.9 (55.1–64.7)	351	88.2 (85.0–91.4)	341	90.2 (87.2–93.2)	350	87.5 (84.3–90.8)	345	85.8 (82.4–89.2)	348	91.6 (88.8–94.4)
	2 products	93	23.2 (19.1–27.3)	45	11.3 (8.2–14.4)	34	9.0 (6.1–11.9)	40	10.0 (7.1–12.9)	48	11.9 (8.8–15.1)	29	7.6 (5.0–10.3)
	>2 products	68	17.0 (13.3–20.6)	2	0.5 (0.0–1.2)	3	0.8 (0.0–1.7)	10	2.5 (1.0–4.0)	9	2.2 (0.8–3.7)	3	0.8 (0.0–1.7)
Product type	1 single-botanical	82	20.5 (16.5–24.4)	172	43.2 (38.3–48.1)	176	46.6 (41.5–51.6)	251	62.8 (58.0–67.5)	212	52.7 (47.9–57.6)	321	84.5 (80.8–88.1)
	1 multi -botanical	158	39.4 (34.6–44.2)	179	45.0 (40.1–49.9)	165	43.7 (38.6–48.7)	99	24.8 (20.5–29.0)	133	33.1 (28.5–37.7)	27	7.1 (4.5–9.7)
	2 or more single-botanical	8	2.0 (0.6–3.4)	12	3.0 (1.3–4.7)	13	3.4 (1.6–5.3)	20	5.0 (2.9–7.1)	26	6.5 (4.1–8.9)	25	6.6 (4.1–9.1)
	2 or more single- and multi-botanical	153	38.2 (33.4–42.9)	35	8.8 (6.0–11.6)	24	6.4 (3.9–8.8)	30	7.5 (4.92–10.1)	31	7.7 (5.1–10.3)	7	1.8 (0.5–3.2)

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Botanicals used

A total of 491 botanicals -used in at least one PFS- were reported across the six participating countries. An overview of all the reported botanicals -clustered by intervals of frequency of intake (number of consumers ranging from 194 to 5)- is shown in Table 12. Based on the survey results, the eleven most frequently used botanicals (numbers of consumers ranging from 194 to 100) in descending order are *Ginkgo biloba* (ginkgo), *Oenothera biennis* (evening primrose), *Cynara scolymus* (artichoke), *Panax ginseng* (ginseng), *Aloe vera* (aloe), *Foeniculum vulgare* (fennel), *Valeriana officinalis* (valerian), *Glycine max* (soybean), *Melissa officinalis* (lemon balm), *Echinacea purpurea* (echinacea) and *Vaccinium myrtillus* (blueberry) (Table 12).

Table 13 shows the overall unweighted ranking of botanicals, 1–40, according to the number of consumers, in decreasing order. Table 13 also shows that when unweighted overall data are stratified by gender, only slight differences between men and women become evident and only *Glycine max* (soybean) was used significantly more by women than by men (Table 13).

When the overall top-40 botanical data are stratified by age groups, slight differences become evident. In the group of 18–59 year-olds, the most frequently used botanicals comply with the overall data just differing in the ranking, with *Oenothera biennis* (evening primrose) being the most frequently used botanical (Table 13). In the group of 60+ year-old a stronger shift can be observed (Table 13). Although *Ginkgo biloba* (ginkgo) is still the most reported botanical -as in the overall ranking- other botanicals are frequently used by that age group. *Harpagophytum procumbens* (devil's claw), *Vaccinium myrtillus* (blueberry) and *Allium sativum* (garlic) are within the most frequently reported botanicals, whereas *Glycine max* (soybean), *Melissa officinalis* (lemon balm) and *Echinacea purpurea* (echinacea) do not appear in the top 10 ranking.

Cross-country differences emerge when considering the overall top-40 botanicals more frequently present in PFS products in each of the individual six countries (Table 14). In the Finnish sample, products containing *Glycine max* (soybean) are the most frequently used, followed by those containing *Echinacea angustifolia and purpurea* (echinacea). German consumers reported *Ginkgo biloba* (ginkgo), *Cynara scolymus* (artichoke) and *Olea europea* (olive) as the most frequently used botanicals; whilst in Romania, *Ginkgo biloba* (ginkgo) was also the ingredient most frequently indicated, followed by *Aloe vera* (aloe) and *Panax ginseng* (ginseng). Amongst Italian consumers, *Aloe vera* (aloe) was the most frequently used botanical, followed by *Foeniculum vulgare* (fennel) and *Valeriana officinalis* (valerian). In Spain, PFS containing *Cynara scolymus* (artichoke) were the most frequently used products, followed by those containing *Valeriana officinalis* (valerian) and *Equisetum arvense* (horsetail). In the United Kingdom, *Oenothera biennis* (evening primrose) was by far the most frequently reported botanical ingredient, followed by *Panax ginseng* (ginseng) and *Hypericum perforatum* (St. John's wort). In addition, there is a great variation in the ranking of consumed botanicals among countries.

Discussion

The present paper reports the findings from a European multi-country survey of PFS consumers: the PlantLIBRA PFS consumer survey. Data on the usage of PFS at the European level are limited, confined in the main to commercial market data [7] as opposed to consumer survey data, as evidenced in the recent review by Bishop and Lewith (2010)[4], where only 13% of population based consumption studies were in Europe. The European Food Safety Authority (EFSA) has recognised the lack of

Table 10. PlantLIBRA's PFS consumer survey – PFS dose forms used, per product used by a respondent, overall and by gender and age group.

Dose forms	Total		Gender				Age group			
	(n = 2874)		Male (n = 1358)		Female (n = 1516)		18–59 years (n = 2131)		≥60 years (n = 743)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Capsules[a]	1101	38.3 (36.5–40.1)	522	38.4 (35.9–41.0)	579	38.2 (35.8–40.6)	844	39.6 (37.5–41.7)	257	34.6 (31.2–38.0)
Pills/tablets/lozenges	1057	36.8 (35.0–38.5)	498	36.7 (34.1–39.2)	559	36.9 (34.4–39.3)	765	35.9 (33.8–37.9)	292	39.3 (35.8–42.8)
Liquid[b]	513	17.9 (16.5–19.3)	238	17.5 (15.5–19.6)	275	18.1 (16.2–20.1)	374	17.6 (15.9–19.2)	139	18.7 (15.9–21.5)
Ampoules	104	3.6 (2.9–4.3)	53	3.9 (2.9–4.9)	51	3.4 (2.5–4.3)	75	3.5 (2.7–4.3)	29	3.9 (2.5–5.3)
Other[c]	99	3.4 (2.8–4.1)	47	3.5 (2.5–4.4)	52	3.4 (2.5–4.4)	73	3.4 (2.7–4.2)	26	3.5 (2.2–4.8)

Question asked. And in which form do you usually take it? (mark the applicable form). *Possible responses*: Pills/tablets/lozenges; Softgel capsules/pearls; Hard capsules; Liquid (extract/syrup/drops); Sachets/packets; Ampoules; Other (specify); Not sure.
[a]Capsules: s°ftgels/pearls/hard capsules.
[b]Liquid: extract/syrups/dr°ps.
[c]Other: P°wders, Sachets/Packets, Bars and "Not sure".
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data in the sector and has published a number of reports addressing related issues [15–16].

To our knowledge this is the first survey of consumers of PFS undertaken in Europe. In total 2359 consumers of PFS were recruited in this cross-sectional retrospective survey. Across all countries prevalence of usage is estimated at 18.8%. Vargas-Murga and colleagues (2011)[9] highlighted that comparable data at European level is difficult to identify when reviewing prevalence data from a selected number of European studies, evaluating PFS or CAM usage, with values ranging from 0.8% to 70%. All studies were based on nationally representative samples but the definition of use of supplements varied widely, in some cases being self-defined by the participant and not distinguishing between PFS and HMP. The use of dietary supplements in a European population was measured in the European Prospective Investigation into Cancer and Nutrition (EPIC) study [8]. Usage was measured by completion of a standardised 24-hour dietary recall and included all dietary supplements that met the EU Directive 2002/46/EC. Results indicated significant differences in overall dietary supplement use between countries with herbs/plant-based supplements representing 8–17% of the products used across the ten countries.

The prevalence rate reported here can be compared to rates from surveys conducted in the United States, where data on usage of dietary supplements, including herbal supplements, is collected more routinely. It is similar to the rate reported in the 2002 and 2007 National Health Interview Surveys (NHIS), 18.9% and 17.9% respectively [20]; higher than the rates of both the Eisenberg's survey [21] and the Slone survey [22], with 14% and 12.1% respectively; and lower than the 2002 Health and Diet Survey (42%) [23] or the 1999 Kaiser Permanent Medical Care Program of Northern California (KPMCP), with a prevalence of 28.3% [24]. These differences in prevalence across studies may in part be due to the distinct selected population samples, survey methodologies (i.e. sampling methods, data collection techniques) or definitions of usage, as well as possible variations in health beliefs and health behaviour of the different populations of study [9], [24].

Survey respondents were recruited to set quotas for both age and gender to reflect characteristics previously reported for dietary supplement users. Age and gender are significant determinants of the consumption of dietary supplements in general and in botanical products in particular. Previous studies on the use of dietary supplements or other herbal-related use show a higher consumption among women as compared to men [1], [17], [24–28] and a higher consumption among older adults as compared to younger adults [24], [29–32].

Table 11. PlantLIBRA's PFS consumer survey – PFS dose forms, per product used by a respondent, by country.

Dose forms	Finland (n = 665)		Germany (n = 446)		Italy (n = 417)		Romania (n = 464)		Spain (n = 465)		United Kingdom (n = 417)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Capsules[a]	206	31.0 (27.5–34.5)	225	50.5 (45.8–55.1)	144	34.5 (30.0–39.1)	82	17.7 (14.2–21.2)	250	53.8 (49.2–58.3)	194	46.5 (41.7–51.3)
Pills/tablets/lozenges	261	39.3 (35.5–43.0)	154	34.5 (30.1–39.0)	126	30.2 (25.8–34.6)	234	50.4 (45.9–55.0)	98	21.1 (17.4–24.8)	184	44.1 (39.4–48.9)
Liquid[b]	174	26.2 (22.8–29.5)	44	9.9 (7.1–12.6)	110	26.4 (22.1–30.6)	82	17.7 (14.2-21.2)	69	14.8 (11.6–18.1)	34	8.2 (5.5–10.8)
Ampoules	0	-	0	-	13	3.1 (1.5–4.8)	47	10.1 (7.4–12.9)	44	9.5 (6.8–12.1)	0	–
Other[c]	24	3.6 (2.2–5.0)	23	5.2 (3.1–7.2)	24	5.8 (3.5–8.0)	19	4.1 (2.3–5.9)	4	0.9 (0.1–1.7)	5	1.2 (0.2–2.2)

Question asked. And in which form do you usually take it? (mark the applicable form). *Possible responses*: Pills/tablets/lozenges; Softgel capsules/pearls; Hard capsules; Liquid (extract/syrup/drops); Sachets/packets; Ampoules; Other (specify); Not sure.
[a]Capsules: softgels/pearls/hard capsules.
[b]Liquid: extract/syrups/drops.
[c]Other: Powders, Sachets/Packets, Bars and "Not sure".
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Table 12. PlantLIBRA's PFS consumer survey – botanicals used by at least 5 respondents, ordered by the "n of respondents".

Used by n≥75 respondents		Used by n≥40-<75 respondents		Used by n ≥20-<40 respondents		Used by n≥5-<20 respondents	
n	**Botanical(s)**	**n**	**Botanical(s)**	**n**	**Botanical(s)**	**n**	**Botanical(s)**
194	*Ginkgo biloba; Oenothera biennis*	74	*Glycyrrhiza glabra*	38	*Cichorium intybus; Malus pumila*	19	*Achillea millefolium; Arctium lappa; Centella asiatica; Punica granatum; Raphanus sativus; Pyrus communis*
177	*Cynara scolymus*	72	*Mentha piperita; Paullinia cupana*	37	*Curcuma longa*	18	*Artemisia absinthium; Pollen; Lecithin*
170	*Panax ginseng*	71	*Malpighia glabra*	36	*Ananas comosus*	17	*Betula pubescens; Spirulina spec.; Vegetable charcoal;*
145	*Aloe vera*	70	*Oenothera spec.*	35	*Daucus carota; Glycine spec.*	16	*Origanum majorana; Ruscus aculeatus;Terminalia chebula*
131	*Foeniculum vulgare ssp*	69	*Silybum marianum*	34	*Myristica fragrans*	15	*Citrus paradise; Eschscholzia californica; Medicago sativa; Picea spec.; Vaccinium oxycoccus; Inulin*
128	*Valeriana officinalis*	66	*Citrus limon; Matricaria chamomilla*	33	*Crataegus monogyna; Cucurbita spec.; Dianthus spec.; Monascus purpureus*	14	*Althaea officinalis; Cuminum cyminum; Eryngium planum; Laminaria digitata; Rhamnus purshianus; Trigonella foenum-graecum; Zea mays*
103	*Glycine max; Melissa officinalis*	64	*Urtica dioica*	32	*Petroselinum crispum; Vaccinium macrocarpon*	13	*Chelidonium majus; Dioscorea villosa; Gossypium spec.; Hyssopus officinalis; Lactuca sativa; Origanum vulgare; Orthosiphon stamineus; Piper nigrum; Theobroma cacao; Trifolium pratense; Uncaria tomentosa; Lycopene; Equisetum spec.; Valeriana spec.*
102	*Echinacea purpurea*	63	*Thymus vulgaris*	31	*Coriandrum sativum; Echinaca spec.; Elettaria cardamomum; Prunus domestica*	12	*Asparagus officinalis; Azadirachta indica; Cassia occidentalis; Eucalyptus globulus; Tagetes erecta; Mentha spec.; Smilax officinalis; Xanthium spinosum*
100	*Vaccinium myrtillus;*	61	*Salvia officinalis*	30	*Cymbopogon citratus; Rhodiola rosea;*	11	*Abies alba; Artemisia abrotanum; Cetraria islandica; Cinnamomum camphora; Ilex paraguariensis; Laurus nobilis; Nasturtium officinale; Salix alba; Tilia spec.; Fraxinus excelsior; Gentiana asclepiadea; Triticum aestivum*
89	*Camellia sinensis; Zingiber officinale*	60	*Cassia senna; Rosmarinus officinalis*	29	*Calendula officinalis*	10	*Aegle marmelos; Aquilegia spec.; Armoracia rusticana; Brassica oleracea ssp.; Cheilocostus speciosus; Kaempferia galangal; Lepidium meyenii; Pimenta dioica; Populus nigra; Potentilla aurea; Santalum spec.; Sida cordifolia; Terminalia arjuna; Thymus serpyllum; Rubus fruticosus; Carlina acaulis; Centaurium spec.; Ganoderma lucidum; Tamarix gallica; Ceratonia siliqua*
88	*Pimpinella anisum*	59	*Hypericum perforatum; Lavandula angustifolia*	28	*Eleutherococcus senticosus; Fucus vesiculosus; Plantago ovate; Solanum lycopersicum; Spirulina platensis; Saccharomyces cerevisiae*	9	*Aesculus hippocastanum; Aloe ferox; Berberis aristata; Brassica oleracea var. botrytis; Capparis spinosa; Capsicum annuum var. annuum; Hieracium pilosella; Opuntia ficus-indica; Serenoa repens; Solanum nigrum; Tribulus terrestris; Melissa spec.*
87	*Vitis vinifera*	58	*Carum carvi*	27	*Citrus aurantium*	8	*Allium cepa; Apium graveolens; Boswellia serrate; Coffea spec.; Euterpe oleracea; Fumaria officinalis; Griffonia simplicifolia; Illicium verum; Malva sylvestris; Prunus armeniaca; Raphanus sativus convar. Sativus; Solidago virgaurea; Tamarindus indica; Carotene; Garcinia cambogia; Soy lecithin*
81	*Taraxacum officinale*	53	*Ribes nigrum*	26	*Schisandra chinensis; Flavonoids; Syzygium aromaticum*	7	*Acorus calamus; Angelica sinensis; Ascophyllum nodosum; Elymus repens; Ficus carica; Hamamelis virginiana; Phaseolus vulgaris; Prunus persica; Rheum spec.; Lutein; Capsicum annuum; Fraxinus spec.; Chamomile Eng; Violeta tricolor;*
79	*Echinacea angustifolia*	52	*Oryza sativa;*	25	*Angelica archangelica; Beta vulgaris ssp. vulgaris var. conditiva; Citrus sinensis; Juniperus communis; Peumus boldus*	6	*Brassica nigra; Brassica oleracea convar. acephala; Capsicum frutescens; Carthamus tinctorius; Cordyceps sinensis; Dioscorea spec.; Drosera rotundifolia; Echinacea pallida; Emblica officinalis; Fallopia japonica; Hedera spec.; Nigella sativa; Plantago psyllium; Satureja hortensis; Tilia platyphyllos; Hibiscus rosa-sinensis; Cirsium spec.; Fragaria spec.; Viola tricolor; Lavandula spec.; Fructooligosaccharides*
78	*Allium sativum Passiflora incarnata;*	48	*Hippophae rhamnoides*	23	*Borago officinalis; Gentiana lutea; Helianthus annuus; Ocimum basilicum; Panicum miliaceum; Pinus spec.*	5	*Aloe spec.; Alpinia galanga; Chamaemelum nobile; Coffea arabica; Cola acuminata; Cyamopsis tetragonoloba; Equisetum telmateia; Fagopyrum esculentum; Hibiscus sabdariffa; Pinus pinaster; Pinus sylvestris; Thymus spec.; Undaria pinnatifida; Withania somnifera; Isoflavones; Arecaceae spec.; Fallopia multiflora*
77	*Linum usitatissimum*	46	*Triticum spec.*	22	*Plantago lanceolata; Rhamnus frangula; Vaccinium vitis-idaea*		

Table 12. Cont.

Used by n≥75 respondents		Used by n≥40-<75 respondents		Used by n ≥20-<40 respondents		Used by n≥5-<20 respondents	
n	Botanical(s)	n	Botanical(s)	n	Botanical(s)	n	Botanical(s)
76	*Equisetum arvense*	43	*Rosa canina; Cinnamomum spec.*	21	*Carica papaya; Cinnamomum verum; Crataegus spec.; Hordeum vulgare; Polygonum aviculare; Saccharum officinarum; Spinacia oleracea*		
75	*Harpagophytum procumbens; Olea europaea*	42	*Sambucus nigra*	20	*Algae; Avena sativa; Betula spec.; Filipendula ulmaria; Humulus lupulus*		

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Other characteristics of dietary supplements users that have been reported previously in the literature include having higher educational attainment and socioeconomic status [24], [33–34], being less likely to smoke [10], [32], [35], being more physically active [10], [29], [32]. Bailey et al. also reported a moderate alcohol consumption (1 drink per day) among dietary supplement users as compared to nonusers. In contrast, a study by Rovira et al. in a southern European population found no differences in lifestyle factors such as physical activity, smoking, and alcohol consumption between dietary supplement users and non-users [36]. Our survey population consists exclusively of PFS consumers, but their responses to a series of questions on health-related lifestyle factors reflect some of the characteristics mentioned above. The majority of PFS consumers perceived their health status to be "very good or good", reflecting results reported in a number of studies on dietary supplement users [32] and CAM and dietary supplement users [24], where the answer "very good or excellent" has been reported for self-reported health status.

The survey results indicate that most consumers reported using one PFS product in the preceding 12 months, with 12% using two products and 4% using more than two. Individual country data show that Finnish consumers use more than one product and PFS with more than one botanical component, and the opposite is observed in the United Kingdom, where about 90% of the consumers use only one PFS and the products contain mostly only one botanical. In the United States, recent studies have reported that about half of the adults report using one or more dietary supplements [32], [37]. One of these studies also found that over half of dietary supplement consumers used a single-botanical product and one third used one multi-botanical product [32]. Similar results were found in our survey across all countries i.e. smaller numbers of consumers reported using two or more single-botanical products (4.4%) and two or more single- and multi-botanical products (11.9%).

A wide variety of botanicals (491) is used in PFS consumed by the respondents in this survey. Overall raw data show that the most frequently (n>100) used botanicals in descending order are *Ginkgo biloba* (ginkgo), *Oenothera biennis* (evening primrose), *Cynara scolymus* (artichoke), *Panax ginseng* (ginseng), *Aloe vera, Foeniculum vulgare* (fennel), *Valeriana officinalis* (valeriana), *Glycine max* (soybean), *Melissa officinalis* (lemon balm), *Echinacea purpurea* (echinacea) *and Vaccinium myrtillus* (blueberry). These results reflect some commercial data which reported that ginkgo followed by echinacea, garlic and ginseng were the four most commercially important botanicals in the combined markets of seventeen EC Member States. In this data, echinacea and ginkgo were part of the composition of products registered as medicines [7], [9], which were excluded from our survey. Similarly, the US Food and Drug Administration 2002 Health and Diet Survey, also a 12-month retrospective study, reported the same four herbs/botanicals/or other nonvitamin-nonmineral dietary supplements being the most used by its adult population – although in the following order: echinacea, garlic, ginkgo and ginseng (the latter including tea) [23]. Schaffer et al. also reported echinacea as the most consumed botanical in the Californian 1999 KPMCP survey, followed by ginkgo [24]. Differences between countries are more evident; the top list of botanicals contained in PFS for each single country complies little with the ranking of the overall data. As mentioned earlier, data were not weighted by country population size because of the study methodology which included very similar country-sample sizes of PFS consumers only, therefore caution is needed when drawing conclusions from these results at the overall 6-country level. Overall data merely describes the collected pooled data from all 6 countries. However, if the overall ranking data were to be

Table 13. PlantLIBRA's PFS consumer survey – distribution of the overall top-40 botanicals' reported consumption and the ranking of these botanicals when stratified by gender and age group.

Botanicals	All consumers			Gender						Age group					
				Male			Female			18-59 years			≥60 years		
	Rank[a]	n	% (95% CI)	Rank[b]	n	% (95% CI)	Rank[b]	n	% (95% CI)	Rank[b]	n	% (95% CI)	Rank[b]	n	% (95% CI)
Ginkgo biloba	1	194	8.2 (7.1–9.3)	1	107	9.4 (7.7–11.0)	3	87	7.1 (5.7–8.6)	2	135	7.7 (6.4–8.9)	1	59	9.9 (7.5–12.3)
Oenothera biennis	2	194	8.2 (7.1–9.3)	3	85	7.5 (5.9–8.9)	1	109	9.0 (7.4–10.5)	1	145	8.2 (6.9–9.5)	2	49	8.2 (6.0–10.4)
Cynara scolymus	3	173	7.3 (6.3–8.4)	5	73	6.4 (5.0–7.8)	2	100	8.2 (6.7–9.7)	4	128	7.3 (6.1–8.4)	4	45	7.6 (5.4–9.6)
Panax ginseng	4	167	7.1 (6.0–8.1)	2	94	8.2 (6.6–9.8)	5	73	6.0 (4.7–7.3)	3	133	7.5 (6.3–8.7)	6	34	5.7 (3.9–7.5)
Aloe vera	5	145	6.2 (5.2–7.1)	4	80	7.0 (5.5–8.5)	7	65	5.3 (4.1–6.6)	5	99	5.6 (4.5–6.7)	3	46	7.7 (5.6–9.8)
Foeniculum vulgare ssp.	6	132	5.6 (4.7–6.5)	7	59	5.2 (3.9–6.4)	4	73	6.0 (4.7–7.3)	6	99	5.6 (4.5–6.7)	7	33	5.6 (3.7–7.3)
Valeriana officinalis	7	125	5.3 (4.4–6.2)	6	62	5.4 (4.1–6.7)	8	63	5.2 (3.9–6.4)	7	97	5.5 (4.4–6.5)	9	28	4.7 (3.0–6.4
Glycine max	8	103	4.4 (3.5–5.2)	24	34	3.0 (2.0–3.9)	6	69	5.7 (4.4–6.9)	10	81	4.6 (3.6–5.5)	14	22	3.7 (2.2–5.2)
Melissa officinalis	9	103	4.4 (3.5–5.2)	8	53	4.7 (3.4–5.8)	10	50	4.1 (3.0–5.2)	9	82	4.7 (3.7–5.6)	17	21	3.5 (2.1–5.0)
Echinacea purpurea	10	102	4.3 (3.5–5.1)	12	43	3.8 (2.7–4.8)	9	59	4.8 (3.6–6.0)	8	83	4.7 (3.7–5.7)	21	19	3.2 (1.8–4.6)
Vaccinium myrtillus	11	100	4.2 (3.4–5.1)	9	53	4.7 (3.4–5.8)	13	47	3.9 (2.8–4.9)	12	71	4.0 (3.1–4.9)	8	29	4.9 (3.1–6.6)
Pimpinella anisum	12	89	3.8 (3.0–4.5)	11	47	4.1 (3.0–5.2)	21	42	3.5 (2.4–4.4)	16	65	3.7 (2.8–4.5)	11	24	4.0 (2.5–5.6)
Zingiber officinale	13	89	3.8 (3.0–4.5)	10	53	4.7 (3.4–5.8)	29	36	3.0 (2.0–3.9)	15	66	3.7 (2.9–4.6)	13	23	3.9 (2.3–5.4)
Camellia sinensis	14	87	3.7 (2.9–4.5)	17	39	3.4 (2.4–4.4)	11	48	3.9 (2.9–5.0)	11	72	4.1 (3.2–5.0)	33	15	2.5 (1.3–3.7)
Vitis vinifera	15	87	3.7 (2.9–4.5)	16	41	3.6 (2.5–4.6)	15	46	3.8 (2.7–4.8)	13	71	4.0 (3.1–4.9)	32	16	2.7 (1.4–4.0)
Taraxacum officinale	16	80	3.4 (2.7–4.1)	21	36	3.2 (2.1–4.1)	17	44	3.6 (2.6–4.6)	17	65	3.7 (2.8–4.5)	34	15	2.5 (1.3–3.7)
Echinacea angustifolia	17	79	3.4 (2.6–4.1)	23	34	3.0 (2.0–3.9)	16	45	3.7 (2.6–4.7)	20	60	3.4 (2.6–4.2)	20	19	3.2 (1.8–4.6)
Passiflora incarnata	18	78	3.3 (2.6–4.0)	30	30	2.6 (1.7–3.5)	12	48	3.9 (2.9–5.0)	19	61	3.5 (2.6–4.3)	30	17	2.9 (1.5–4.2)
Linum usitatissimum	19	77	3.3 (2.6–4.0)	13	43	3.8 (2.7–4.8)	33	34	2.8 (1.9–3.7)	22	56	3.2 (2.4–4.0)	16	21	3.5 (2.1–5.0)
Equisetum arvense	20	76	3.2 (2.5–3.9)	19	37	3.2 (2.2–4.2)	23	39	3.2 (2.2–4.2)	23	55	3.1 (2.3–3.9)	15	21	3.5 (2.1–5.0)
Allium sativum	21	75	3.2 (2.5–3.9)	28	32	2.8 (1.9–3.7)	18	43	3.5 (2.5–4.5)	29	50	2.8 (2.1–3.6)	10	25	4.2 (2.6–5.8)
Harpagophytum procumbens	22	75	3.2 (2.5–3.9)	18	39	3.4 (2.4–4.4)	26	36	3.0 (2.0–3.9)	40	40	2.3 (1.6–2.9)	5	35	5.9 (4.0–7.7)
Olea europaea	23	75	3.2 (2.5–3.9)	27	33	2.9 (1.9–3.8)	20	42	3.5 (2.4–4.4)	24	55	3.1 (2.3–3.9)	19	20	3.4 (1.9–4.8)
Glycyrrhiza glabra	24	74	3.1 (2.4–3.8)	26	33	2.9 (1.9–3.8)	22	41	3.4 (2.4–4.4)	25	54	3.1 (2.3–3.8)	18	20	3.4 (1.9–4.8)
Mentha piperita	25	72	3.1 (2.4–3.8)	20	36	3.2 (2.1–4.1)	27	36	3.0 (2.0–3.9)	27	53	3.0 (2.2–3.8)	22	19	3.2 (1.8–4.6)
Paullinia cupana	26	72	3.1 (2.4–3.8)	14	43	3.8 (2.7–4.8)	38	29	2.4 (1.5–3.2)	14	66	3.7 (2.9–4.6)	74	6	1.0 (0.2–1.8)
Malpighia glabra	27	71	3.0 (2.3–3.7)	15	41	3.6 (2.5–4.6)	37	30	2.5 (1.6–3.3)	18	61	3.5 (2.6–4.3)	51	10	1.7 (0.7–2.7)
Oenothera spec	28	70	3.0 (2.3–3.7)	41	23	2.0 (1.2–2.8)	14	47	3.9 (2.8–4.9)	21	59	3.3 (2.5–4.2)	47	11	1.9 (0.8–2.9)
Silybum marianum	29	69	2.9 (2.2–3.6)	25	34	3.0 (2.0–3.9)	30	35	2.9 (1.9–3.8)	32	46	2.6 (1.9–3.3)	12	23	3.9 (2.3–5.4)
Matricaria chamomilla	30	67	2.8 (2.2–3.5)	34	29	2.5 (1.6–3.4)	25	38	3.1 (2.1–4.1)	26	54	3.1 (2.3–3.8)	38	13	2.2 (1.0–3.3)
Citrus limon	31	66	2.8 (2.1–3.5)	37	24	2.1 (1.3–2.9)	19	42	3.5 (2.4–4.4)	30	48	2.7 (2.0–3.5)	25	18	3.0 (1.7–4.4)
Urtica dioica	32	64	2.7 (2.1–3.4)	31	30	2.6 (1.7–3.5)	34	34	2.8 (1.9–3.7)	28	51	2.9 (2.1–3.7)	37	13	2.2 (1.0–3.3)
Thymus vulgaris	33	63	2.7 (2.0–3.3)	36	28	2.5 (1.6–3.3)	31	35	2.9 (1.9–3.8)	33	44	2.5 (1.8–3.2)	24	19	3.2 (1.8–4.6)
Salvia officinalis	34	61	2.6 (2.0–3.2)	32	22	1.9 (1.1–2.7)	35	39	3.2 (2.2–4.2)	34	43	2.4 (1.7–3.1)	29	18	3.0 (1.7–4.4)
Cassia senna	35	60	2.5 (1.9–3.2)	43	29	2.5 (1.6–3.4)	24	31	2.6 (1.7–3.4)	37	43	2.4 (1.7–3.1)	28	17	2.9 (1.5–4.2)
Rosmarinus officinalis	36	60	2.5 (1.9–3.2)	38	24	2.1 (1.3–2.9)	28	36	3.0 (2.0–3.9)	39	41	2.3 (1.6–3.0)	23	19	3.2 (1.8–4.6)
Carum carvi	37	59	2.5 (1.9–3.1)	22	35	3.1 (2.1–4.0)	43	24	2.0 (1.2–2.7)	31	46	2.6 (1.9–3.3)	36	13	2.2 (1.0–3.3)
Hypericum perforatum	38	59	2.5 (1.9–3.1)	29	31	2.7 (1.8–3.6)	39	28	2.3 (1.5–3.1)	35	43	2.4 (1.7–3.1)	31	16	2.7 (1.4–4.0)
Lavandula angustifolia	39	57	2.4 (1.8–3.0)	40	23	2.0 (1.2–2.8)	32	34	2.8 (1.9–3.7)	36	43	2.4 (1.7–3.1)	35	14	2.4 (1.1–3.5)
Ribes nigrum	40	53	2.3 (1.7–2.8)	42	22	1.9 (1.1–2.7)	36	31	2.6 (1.7–3.4)	38	41	2.3 (1.6–3.0)	41	12	2.0 (0.9–3.1)

[a]Products ordered according to the consumer distribution of the overall top-40 used botanicals (unweighted ranking).
[b]Ranks show the shifts of the botanicals in the position of the overall 1–40 unweighted ranking when stratified by gender and age group.
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weighted by the population size -for example the 1–5 ranking data-, the positions of the botanicals would have been only slightly altered, with *Oenothera biennis* (evening primrose) being the most consumed one, followed by *Cynara scolymus* (artichoke) *Ginkgo biloba* (ginkgo), *Panax ginseng* (ginseng) and *Aloe vera* (aloe).

The results of the survey highlight clear differences between countries in terms of the botanicals used by consumers as PFS.

Table 14. PlantLIBRA's PFS consumer survey – ranking of the overall top-40 botanicals' reported consumption when stratified by country.

Botanicals	Finland			Germany			Italy			Romania			Spain			United Kingdom		
	Rank[a]	n	% (95% CI)	Rank[a]	n	% (95% CI)	Rank[a]	n	% (95% CI)	Rank[a]	n	% (95% CI)	Rank[1]	n	% (95% CI)	Rank[a]	n	% (95% CI)
Ginkgo biloba		0	-	1	50	12.6 (9.3–15.8)	12	17	4.5 (2.4–6.6)	1	105	26.3 (21.9–30.6)	27	11	2.7 (1.1–4.3)	11	11	2.9 (1.2–4.6)
Oenothera biennis		0	-	22	15	3.8 (1.9–5.6)	174	1	0.3 (0.0–0.8)	164	1	0.3 (0.0–0.7)	20	13	3.2 (1.5–5.0)	1	164	43.2 (38.2–48.1)
Cynara scolymus	53	12	3.0 (1.3–4.7)	2	47	11.8 (8.6–15.0)	10	20	5.3 (3.0–7.6)	7	27	6.8 (4.3–9.2)	1	67	16.7 (13.0–20.3)		0	–
Panax ginseng	42	16	4.0 (2.1–5.9)	7	26	6.5 (4.1–9.0)	4	28	7.4 (4.8–10.1)	3	41	10.3 (7.3–13.2)	16	15	3.7 (1.9-5.6)	2	41	10.8 (7.7–13.9)
Aloe vera	172	1	0.3 (0.0–0.7)	25	12	3.0 (1.3–4.7)	1	44	11.6 (8.4–14.9)	2	47	11.8 (8.6–14.9)	37	8	2.0 (0.6–3.4)	4	33	8.7 (5.9–11.5)
Foeniculum vulgare ssp.	31	21	5.2 (3.1–7.4)	11	20	5.0 (2.9–7.2)	2	29	7.7 (5.0–10.4)	8	27	6.8 (4.3–9.2)	4	34	8.5 (5.7–11.2)	33	1	0.3 (0.0–0.8)
Valeriana officinalis	192	1	0.3 (0.0–0.7)	19	16	4.0 (2.1–6.0)	3	29	7.7 (5.0–10.4)	43	11	2.8 (1.2–4.4)	2	51	12.7 (9.4–15.9)	6	17	4.5 (2.4–6.6)
Glycine max	1	73	18.2 (14.4–22.0)	6	27	6.8 (4.3–9.3)	161	1	0.3 (0.0–0.8)		0	-	114	2	0.5 (0.0–1.2)		0	-
Melissa officinalis	14	39	9.7 (6.8–12.6)	12	20	5.0 (2.9–7.2)	7	25	6.6 (4.1–9.1)	74	5	1.3 (0.2–2.3)	18	14	3.5 (1.7–5.3)		0	-
Echinacea purpurea	3	55	13.7 (10.3–17.1)		0	-	59	5	1.3 (0.2–2.5)	13	24	6.0 (3.7–8.3)	70	4	1.0 (0.0–2.0)	7	14	3.7 (1.8–5.6)
Vaccinium myrtillus	23	30	7.5 (4.9–10.1)	30	12	3.0 (1.3–4.7)	5	28	7.4 (4.8–10.1)	15	20	5.0 (2.9–7.1)	43	8	2.0 (0.6–3.4)	26	2	0.5 (0.0–1.3)
Pimpinella anisum	16	36	9.0 (6.2–11.8)	28	12	3.0 (1.3–4.7)	38	8	2.1 (0.7–3.6)	21	15	3.8 (1.9–5.6)	11	18	4.5 (2.5–6.5)		0	–
Zingiber officinale	13	41	10.2 (7.3–13.2)	36	11	2.8 (1.2–4.4)	67	5	1.3 (0.2–2.5)	4	30	7.5 (4.9–10.1)	131	2	0.5 (0.0–1.2)		0	–
Camellia sinensis	28	23	5.7 (3.5–8.0)	16	16	4.0 (2.1–6.0)	22	12	3.2 (1.4–4.9)	47	10	2.5 (1.0–4.0)	6	26	6.5 (4.1–8.9)		0	–
Vitis vinifera	34	20	5.0 (2.9–7.1)	5	28	7.0 (4.5–9.6)	28	11	2.9 (1.2–4.6)	127	2	0.5 (0.0–1.2)	12	18	4.5 (2.5–6.5)	13	8	2.1 (0.7–3.6)
Taraxacum officinale	65	10	2.5 (1.0–4.0)	52	10	2.5 (1.0–4.1)	9	21	5.6 (3.2–7.9)	24	15	3.8 (1.9–5.6)	8	24	6.0 (3.7–8.3)		0	–
Echinacea angustifolia	2	55	13.7 (10.3–17.1)		0	–	48	6	1.6 (0.3–2.9)	117	2	0.5 (0.0–1.2)	31	10	2.5 (1.0–4.0)	15	6	1.6 (0.3–2.8)
Passiflora incarnata	75	8	2.0 (0.6–3.4)	62	7	1.8 (0.5–3.1)	6	26	6.9 (4.3–9.4)	65	7	1.8 (0.5–3.0)	5	30	7.5 (4.9–10.0)		0	–
Linum usitatissimum	24	28	7.0 (4.5–9.5)	27	12	3.0 (1.3–)4.7	95	3	0.8 (0.0–1.7)	14	24	6.0 (3.7–8.3)	73	4	1.0 (0.0–2.0)	16	6	1.6 (0.3–2.8)
Equisetum arvense	26	26	6.5 (4.1–8.9)	153	1	0.3 (0.0–0.7)	60	5	1.3 (0.2–2.5)	82	4	1.0 (0.0–2.0)	3	40	10.0 (7.0–12.9)		0	–
Allium sativum	27	25	6.2 (3.9–8.6)	92	3	0.8 (0.0–1.6)	69	4	1.1 (0.0–2.1)	64	7	1.8 (0.5–3.0)	7	24	6.0 (3.7–8.3)	10	12	3.2 (1.4–4.9)
Harpagophytum procumbens		0	–	9	21	5.3 (3.1–7.5)	20	13	3.4 (1.6–5.3)	55	9	2.3 (0.8–3.7)	40	8	2.0 (0.6–3.4)	5	24	6.3 (3.9–8.8)
Olea europaea	30	22	5.5 (3.3–7.7)	3	40	10.1 (7.1–13.0)		0	–	84	4	1.0 (0.0–2.0)	42	8	2.0 (0.6–3.4)	36	1	0.3 (0.0–0.8)
Glycyrrhiza glabra	47	14	3.5 (1.7–5.3)	18	16	4.0 (2.1–6.0)	17	14	3.7 (1.8–5.6)	10	26	6.5 (4.1–8.9)	71	4	1.0 (0.0–2.0)		0	–
Mentha piperita	4	47	11.7 (8.6–14.9)	24	14	3.5 (1.7–5.3)	78	4	1.1 (0.0–2.1)	75	5	1.3 (0.2–2.3)	119	2	0.5 (0.0–1.2)		0	–
Paullinia cupana	130	4	1.0 (0.0–2.0)	10	21	5.3 (3.1–7.5)	8	23	6.1 (3.7–8.5)	76	5	1.3 (0.2–2.3)	14	16	4.0 (2.1–5.9)	21	3	0.8 (0.0–1.7)
Malpighia glabra	12	41	10.2 (7.3–13.2)	21	15	3.8 (1.9–5.6)	18	14	3.7 (1.8–5.6)		0	–	169	1	0.3 (0.0–0.7)		0	–
Oenothera spec	10	43	10.7 (7.7–13.8)		0	–		0	–		0	–	10	20	5.0 (2.9–7.1)	14	7	1.8 (0.5–3.2)
Silybum marianum	190	1	0.3 (0.0–0.7)	35	11	2.8 (1.2–4.4)	15	15	4.0 (2.0–5.9)	23	15	3.8 (1.9–5.6)	19	14	3.5 (1.7–5.3)	9	13	3.4 (1.6–5.3)
Matricaria chamomilla	66	10	2.5 (1.0–4.0)	38	11	2.8 (1.2–4.4)	35	9	2.4 (0.8–3.9)	20	16	4.0 (2.1–5.9)	9	21	5.2 (3.1–7.4)		0	–
Citrus limon	7	43	10.7 (7.7–13.8)	112	2	0.5 (0.0–1.2)	29	10	2.7 (1.0–4.3)	146	1	0.3 (0.0–0.7)	30	10	2.5 (1.0–4.0)		0	–
Urtica dioica	9	43	10.7 (7.7–13.8)	53	10	2.5 (1.0–4.1)	133	2	0.5 (0.0–1.3)	89	4	1.0 (0.0–2.0)	66	5	1.2 (0.2–2.3)		0	–
Thymus vulgaris	6	47	11.7 (8.6–14.9)	177	1	0.3 (0.0–0.7)	66	5	1.3 (0.2–2.5)	87	4	1.0 (0.0–2.0)	53	6	1.5 (0.3–2.7)		0	–
Salvia officinalis	8	43	10.7 (7.7–13.8)	80	5	1.3 (0.2–2.4)	82	4	1.1 (0.0–2.1)	66	7	1.8 (0.5–3.0)	124	2	0.5 (0.0–1.2)		0	–

Table 14. Cont.

Botanicals	Finland			Germany			Italy			Romania			Spain			United Kingdom		
	Rank[a]	n	% (95% CI)	Rank[a]	n	% (95% CI)	Rank[a]	n	% (95% CI)	Rank[a]	n	% (95% CI)	Rank[1]	n	% (95% CI)	Rank[a]	n	% (95% CI)
Cassia senna		0	–		0	–	11	19	5.0 (2.8–7.2)	11	25	6.3 (3.9–8.6)	22	12	3.0 (1.3–4.7)	17	4	1.1 (0.0–2.1)
Rosmarinus officinalis	64	10	2.5 (1.0–4.0)	34	11	2.8 (1.2–4.4)	129	2	0.5 (0.0–1.3)	12	25	6.3 (3.9–8.6)	25	12	3.0 (1.3–4.7)		0	–
Carum carvi		0	–	8	23	5.8 (3.5–8.1)	33	9	2.4 (0.8–3.9)	9	26	6.5 (4.1–8.9)	149	1	0.3 (0.0–0.7)		0	–
Hypericum perforatum		0	–	157	1	0.3 (0.0–0.7)	34	9	2.4 (0.8–3.9)	56	9	2.3 (0.8–3.7)	63	5	1.2 (0.2–2.3)	3	35	9.2 (6.3–12.1)
Lavandula angustifolia	17	34	8.5 (5.8–11.2)	161	1	0.3 (0.0–0.7)		0	–	60	8	2.0 (0.6–3.4)	32	10	2.5 (1.0–4.0)	19	4	1.1 (0.0–2.1)
Ribes nigrum	20	32	8.0 (5.3–10.6)	172	1	0.3 (0.0–0.7)	44	7	1.9 (0.5–3.2)	176	1	0.3 (0.0–0.7)	24	12	3.0 (1.3–4.7)		0	–

[a]Ranks show the shifts of the botanicals in the position of the overall 1–40 unweighted ranking when stratified by country.
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This may reflect the fact that the current legal and regulatory framework for botanicals has a major influence on the nature of the local PFS markets. The EU Directive 2002/46/EC does not provide a clear definition of what is encompassed by the term 'other substance with a nutritional or physiological effect', although it is generally accepted that botanicals and their extracts fall into this category. Current legislation varies across Europe, with significant differences in the botanical species permitted in PFS. These issues were highlighted in a recent review of the regulations applicable to PFS in the European Union by Silano et al. [38]. They provide examples of the different national approaches for the use of selected botanicals in food supplements in the EU Member States.

To illustrate the above complexity, in Germany, food supplements are regulated by the German Regulation on Food Supplements [39] and the German Law on Food and Feed [40]. Positive lists are available for minerals and vitamins. Food supplements have to be registered with the Federal Office of Consumer Protection and Food Safety [41]. The BVL maintains a list of plants which are either classified as a food or a medicinal product, and which is neither considered complete nor legally binding [41]. Data on the intake of PFS in Germany is limited and, despite food supplement intake being recorded in recent health and nutrition surveys [42–44], no specific data was published on PFS intake. The results from the PlantLIBRA consumer survey do not include *Valeriana officinalis* in the German top list of botanicals used in PFS, whereas 1852 medicinal products containing Valerian exist on the market [40]. The absence of *Valeriana officinalis* in the German list of botanicals can be explained by its dominant presence as a HMP in the German market.

The results of this survey represent some of the first data on the usage of PFS at European level, thus addressing the existing deficit of such data by collecting retrospective data directly from consumers in six European countries. The benefits of the data collection instrument used in this study included that it was relatively straightforward to administer, did not alter habitual usage patterns and allowed the classification of individuals into categories of usage. However, the results must be considered in the light of their limitations. The sample population comprises exclusively of PFS consumers, recruited to meet very specific inclusion criteria and hence no comparisons can be made with the general population. Future studies should seek to compare users and non-users of PFS.

Further limitations relate to the retrospective nature of the data being collected. In many cases respondents needed to rely on memory to report usage of products in the preceding 12 months. Where products are available for inspection at data collection, there is a need for careful recording of product details to ensure accurate coding. The lack of a comprehensive product database containing reliable ingredient information meant a bespoke database needed to be created. Future studies should seek to collect prospective data. Prospective dietary intake surveys offer an ideal opportunity to collect data on supplement use in conjunction with data on food and beverages. Care needs to be taken to collect sufficiently detailed information about ingredients and amounts consumed. For example, in the US, the Alternative Health/CAM supplement of the National Health Interview Survey (NHIS) is part of an annual, nationally representative survey of US adults. It contains data on adults' use of 10 herbs most commonly taken to treat a specific health condition in the preceding 12 months [13]; the survey has a separate section on dietary supplements and distinguishes "natural herbs" from vitamins and minerals. The authors would like to encourage researchers to implement future surveys/studies which are necessary to overcome the bottlenecks in PFS risk and benefit assessments at the European level.

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Author Contributions

Wrote the paper: AGA BE MMR. Responsible for the survey: LSM. Coordination of the survey: AGA. Study design: LSM LRB VK AGA BE SDK LD FMM MS MMR MB FB. Material elaboration: AGA VK BE SDK LD FMM MS LRB MMR EMM MB FB. Data reviewing/handling/cleaning: AGA BE LD FMM MI LRB SDK EMM MB FB MS CH AM LU. Data analysis strategy: LRB LSM AGA RMV BE MMR SDK LD FMM MI EMM MB FB MS CH AM LU. Data handling and analysis: RMV LRB AGA. Drafts reviews: AGA LRB EMM SDK LD FMM BE MMR MB AM VK LU MS PR LSM. Manuscript coordination: AGA.

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ANNEX IVd - Poster:

Plant food supplement consumption, body weight control and BMI: results from the PlantLIBRA PFS Consumer Survey 2011-2012.

Presented at the *III World Congress of Public Health Nutrition*
Las Palmas de Gran Canaria
11th November 2014

Plant food supplement consumption, body weight control and BMI: results from the PlantLIBRA PFS Consumer Survey 2011-2012.

nutrition 2014
Las Palmas de Gran Canaria SPAIN
Baniul GAMBIA

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Objectives

To provide an overview of the PFS botanical ingredients consumed for "body weight reasons" and by "dieters for overweight/obesity" in six European countries, and to explore the relationship between the consumption of these botanical ingredients and the self-reported BMI of their consumers.

Methods

This study has been carried out within the PlantLIBRA project (FP7-EC funded project nº245199). Data on PFS usage were collected in Finland, Germany, Italy, Romania, Spain and the United Kingdom, in a cross-sectional, retrospective survey of 2359 PFS consumers using a bespoke frequency-of-PFS-usage questionnaire. Analyses were performed in two subsamples of 1) respondents taking the products for "body weight reasons", and 2) "overweight/obesity dieters". Subsamples' country proportions are presented; consumed PFS botanicals by respondents of "body weight reasons", by "overweight/obesity dieters" and by the "crosstab of the two" are identified. The relationship between the 5 most consumed botanicals and self-reported BMI in group 1 and 2 is explored by comparing BMI proportions of consumers *vs.* non-consumers (using Chi-squared test, $p<0.05$ for significance). Comparisons are made using a) the "body weight reason" sample (n=240) and "overweight/obesity dieters" sample (n=112), in which the top 5 consumed botanicals have actually been identified, and b) the total survey sample (N=2359) in order to increase the power of the test.

Results

Figure 1: Of the total 2874 PFS products consumed in the survey, 252 (8.8%) products were reported to be consumed for "body weight reasons" (reported by 240 PFS consumers), Spain being the country with the most PFS taken for this reason (21.5%).

Figure 2: Of the total 2359 PFS consumers of the survey, 112 (4.8%) reported to be "dieting for overweight/obesity", Spain being the country with most dieters.

Figure 1. PFS products taken for "body weight" (%), by country

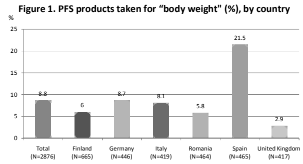
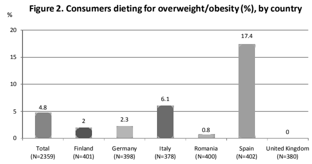


Figure 2. Consumers dieting for overweight/obesity (%), by country



Figures 3-5 show the top 5 botanicals consumed by each of the two groups of analysis (Figure 3 and 4), and by a third group that crosstabs both of them, i.e. the respondents of "body weight reason" who are also "overweight/obesity dieters" (Figure 5). Artichoke is the most consumed botanical by consumers of all three groups, and it is followed by green tea in the first group and by fennel in the other two groups.

Figure 3. Top 5 botanicals consumed for "body weight reasons" (%) (N=240)

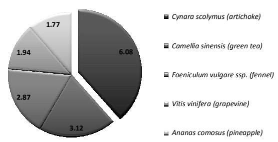


Figure 4. Top 5 botanicals consumed by "overweight/obesity dieters" (%) (N=112)

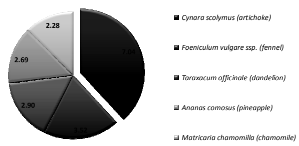


Figure 5. Top 5 consumed botanicals by respondents of "body weight reason" who are also "overweight/obesity dieters" (%) (N=67)

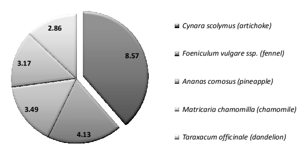


Table 1 shows BMI differences between consumers and non-consumers of the top 5 botanicals consumed for "body weight reasons", when using a) the respondents of "body weight reasons" sample or b) the entire survey sample. In case "a", no significant differences are observed. However in case "b", a **greater** proportion of consumers of PFS containing artichoke and green tea have a BMI≥25 kg/m² as compared to non-consumers (p=0.019 and p=0.043 respectively).

Table 2 shows BMI differences between consumers and non-consumers of the top 5 botanicals consumed by "overweight/obesity dieters", when using a) the "dieters" sample or b) the entire survey sample. In case "a", the proportion of BMI≥25 is **lower** among consumers of pineapple-containing PFS as compared to non-consumers (p=0.000). In case "b", the proportion of BMI≥25 is **greater** among consumers of artichoke-containing PFS than among non-consumers (p=0.019).

Table 1. BMI distribution differences between consumers and non-consumers of the top 5 botanicals consumed by those who responded "body weight reasons" for PFS use.

		BMI				
		<25 kg/m²		≥25 kg/m²		
Top 5 consumed botanicals for "body weight"	Consumption group	n	%	n	%	Chi-squared p-value
a) When using only the subsample of consumers responding "body weight" (N=240)						
Cynara scolymus (artichoke)	Consumers	24	33.3	48	66.7	0.168
	Non-consumers	72	42.9	96	57.1	
Foeniculum vulgare ssp. (fennel)	Consumers	15	40.5	22	59.5	0.942
	Non-consumers	81	39.9	122	60.1	
Camellia sinensis (green tea)	Consumers	17	50	17	50	0.199
	Non-consumers	79	38.3	127	61.7	
Vitis vinifera (grapevine)	Consumers	6	26.1	17	73.9	0.152
	Non-consumers	90	41.5	127	58.5	
Ananas comosus (pineapple)	Consumers	10	47.6	11	52.4	0.456
	Non-consumers	86	39.3	133	60.7	
b) When using the entire sample of consumers (N=2359)						
Cynara scolymus (artichoke)	Consumers	72	41.6	101	58.4	0.019
	Non-consumers	1113	50.9	1073	49.1	
Foeniculum vulgare ssp. (fennel)	Consumers	71	53.8	61	46.2	0.401
	Non-consumers	1114	50	1113	50	
Camellia sinensis (green tea)	Consumers	32	36.7	55	63.2	0.043
	Non-consumers	1142	50.3	1130	49.7	
Vitis vinifera (grapevine)	Consumers	43	49.4	44	50.6	0.878
	Non-consumers	1142	50.3	1130	49.7	
Ananas comosus (pineapple)	Consumers	21	60	14	40	0.244
	Non-consumers	1164	50.1	1160	49.9	

Table 2. BMI distribution differences between consumers and non-consumers of the top 5 botanicals consumed by "overweight/obesity dieters".

		BMI				
		<25 kg/m²		≥25 kg/m²		
Top 5 consumed botanicals by "dieters for overweight/obesity"	Consumption group	n	%	n	%	Chi-squared p-value
a) When using only the subsample of consumers responding to be "dieting for overweight/obesity" (N=112)						
Cynara scolymus (artichoke)	Consumers	9	26.5	25	73.5	0.590
	Non-consumers	17	21.8	61	78.2	
Foeniculum vulgare ssp. (fennel)	Consumers	5	29.4	12	70.6	0.511
	Non-consumers	21	22.1	74	77.9	
Taraxacum officinale (dandelion)	Consumers	3	21.4	11	78.6	0.866
	Non-consumers	23	23.5	75	76.5	
Ananas comosus (pineapple)	Consumers	8	61.5	5	38.5	0.000
	Non-consumers	18	18.2	81	81.8	
Matricaria chamomilla (chamomile)	Consumers	1	9.1	10	90.9	0.243
	Non-consumers	25	24.8	76	75.2	
b) When using the entire sample of consumers (N=2359)						
Cynara scolymus (artichoke)	Consumers	72	41.6	101	58.4	0.019
	Non-consumers	1113	50.9	1073	49.1	
Foeniculum vulgare ssp. (fennel)	Consumers	71	53.8	61	46.2	0.401
	Non-consumers	1114	50	1113	50	
Taraxacum officinale (dandelion)	Consumers	39	48.8	41	51.3	0.787
	Non-consumers	1146	50.3	1133	49.7	
Ananas comosus (pineapple)	Consumers	21	60	14	40	0.244
	Non-consumers	1164	50.1	1160	49.9	
Matricaria chamomilla (chamomile)	Consumers	32	47.8	35	52.2	0.681
	Non-consumers	1153	50.3	1139	49.7	

Note: BMI differences among consumers and non-consumers of botanicals taken by the third group could not be analysed due to the small size of some cells. For the same reason country comparisons could not either be performed.

Conclusions

This is the first study that has identified the most consumed botanicals for "body weight reasons" in PFS consumers from 6 EU countries; moreover, it has identified the most consumed botanicals by "overweight/obesity dieters" and, finally, by the "body weight respondents" who are simultaneously "on a diet for overweight/obesity*"* (and who could ultimately be considered the "weight-loss PFS consumers" of the PlantLIBRA PFS Consumer Survey). Spain is the country where consuming botanicals for "body weight" and "dieting" are most prevalent. Artichoke is in all three groups the most consumed botanical, followed by fennel in two groups. Using the smaller "dieters" sample, pineapple consumers seem to be significantly less overweight/obese. When using the larger comparison sample, in respondents of "body weight reasons", consumers of artichoke- and green tea-containing PFS are significantly more overweight/obese as compared to non-consumers; this is also observed for artichoke consumers when using the "dieters" larger sample. We do not know why this is happening, and we cannot infer causality from these results due to the cross-sectional nature of the survey. The actual botanicals consumed are meant to have "body weight control/loss" properties, although the literature/evidence for most of them is inconclusive. It would be important to have data on the exact amounts of the botanicals contained in the products consumed in order to differentiate the "essential body-weight-control" botanical from the "complementary" botanical within the multi-ingredient weight-loss product. The authors would like to encourage the research community to carry out further studies on this topic, with larger sample sizes from the general population (PFS consumers and non-consumers - ideally as part of regional/national health/nutrition surveys), collecting label data on ingredients amounts. This additional information would help elucidate the many unknowns about the effectiveness of PFS used as a strategy for body weight control.

PlantLIBRA
EC project number 245199

Acknowledgements:

SEVENTH FRAMEWORK PROGRAMME

RESUMEN EN CASTELLANO DE LA TESIS DOCTORAL[1]: ASPECTOS MÁS RELEVANTES

"El sobrepeso y la obesidad en relación al estado socio-económico, el tabaquismo y el uso de complementos alimenticios a base de plantas"

Alicia García Álvarez

[1] Se incluye este resumen en castellano cumpliendo con la normativa del "Reglamento para la elaboración, tribunal, defensa y evaluación de tesis doctorales, Capítulo I, Artículo 2" (Real Decreto 1393/2007), de la Universidad de Las Palmas de Gran Canaria.

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Abreviaturas

CA	Complementos alimenticios
CAP	Complementos alimenticios a base de plantas
CE	Comisión Europea
EAS	European Advisory Services
ENCAT	Evaluación del estado nutricional de la población catalana
GHO	Global Health Observatory
IASO	International Association for the Study of Obesity
IMC	Índice de Masa Corporal
IOTF	International Obesity Task Force
OMS	Organización Mundial de la Salud
PC	Perímetro de la cintura
PlantLIBRA	PLANT food supplements: Levels of Intake, Benefit and Risk Assessment
RA PC	Riesgo aumentado de enfermedad metabólica por PC
RAS PC	Riesgo aumentado sustancialmente de enfermedad metabólica por PC
UE	Unión Europea
WHO	World Health Organization
CA	Complementos alimenticios

I. MOTIVACIÓN, OBJETIVO PRINCIPAL Y OBJETIVOS ESPECÍFICOS

Motivación

Las tasas de prevalencia del sobrepeso y la obesidad han aumentado en todo el mundo en las últimas décadas. Este es también el caso de la población adulta de Cataluña, España.

El sobrepeso y la obesidad son enfermedades crónicas multifactoriales.

Son múltiples las estrategias utilizadas por las personas para el control/pérdida del peso corporal. Aunque las dietas de todo tipo y la actividad física son los métodos más populares, también son relevantes el consumo de tabaco (por ejemplo, los fumadores son reacios a dejar de fumar porque creen que ello les llevará a aumentar de peso) y el uso de complementos alimenticios a base de plantas (CAP).

Esta tesis doctoral ha sido motivada por las siguientes preguntas:
1. ¿Cuáles son las tasas de prevalencia de sobrepeso y obesidad en la población adulta catalana en dos períodos diferentes en el tiempo (1992-1993 y 2002-2003)?
2. ¿Existe alguna relación entre las tasas de prevalencia y factores socioeconómicos (ocupación y educación) y socio-demográficos (sexo, edad y tamaño de la población de residencia)?
3. ¿Existe alguna relación entre las tasas de prevalencia y las estrategias de control de peso utilizadas popularmente como el consumo de tabaco (en Cataluña) y el consumo de CAP (en seis países de la UE)?

Objetivo principal

Esta tesis doctoral pretende dar respuesta a las preguntas formuladas en la motivación, con la intención de identificar los grupos vulnerables dentro de la población Catalana adulta que -según su estado socio-económico o su hábito tabáquico- puedan verse más afectados por el sobrepeso y la obesidad. Además, se pretende comprobar si fumar o consumir CAP para controlar o perder peso está relacionado con el sobrepeso o la obesidad. Por último, se pretende contribuir a la literatura científica relacionada con el sobrepeso y la obesidad.

Objetivos específicos

Los objetivos del capítulo 1 son dos: a) evaluar las tendencias (1992-2003) de las tasas de prevalencia de sobrepeso y obesidad en la población adulta de Cataluña, España, y b) explorar la influencia de algunas variables socioeconómicas (ocupación y educación) y socio-demográficas (sexo, edad y tamaño de la población de residencia) en estas tendencias de prevalencia.

El capítulo 2 examina las tendencias en la relación entre el historial tabáquico y el sobrepeso/obesidad, y entre el historial tabáquico y la adiposidad central en una población de adultos catalanes.

El capítulo 3 tiene como objetivo ofrecer una visión general de las características y los patrones de uso de los consumidores de CAP en seis países europeos. Este capítulo también contextualiza el trabajo llevado a cabo en el capítulo 4 de la tesis.

Por último, los objetivos del capítulo 4 son dos: a) proporcionar una visión general de los ingredientes botánicos de los CAP consumidos por "razones de peso corporal" y por "personas que hacen dieta contra el sobrepeso/obesidad" en seis países europeos, y b) explorar la relación entre el consumo de estos ingredientes botánicos y el Índice de Masa Corporal (IMC) auto-informado de sus consumidores.

II. PLANTEAMIENTO Y METODOLOGÍA

1. Antecedentes

En esta sección se introducen los principales objetivos de investigación desarrollados en la tesis doctoral. La sección 1.1 muestra la importancia de los problemas de obesidad y sobrepeso (exceso ponderal y adiposidad) en la sociedad actual. Se definen la obesidad y el sobrepeso, se explican las técnicas de medición del peso y la grasa corporales, y se describen los indicadores de peso general y grasa abdominal utilizados en el análisis empírico (Índice de Masa Corporal –IMC- y Perímetro de la Cintura -PC). También se muestran las tasas de prevalencia y tendencias actuales de sobrepeso y obesidad a nivel mundial, europeo y español; los factores determinantes del sobrepeso y la obesidad; y los efectos que el sobrepeso y la obesidad ejercen sobre la salud. Todos estos aspectos han sido ampliamente descritos en numerosos artículos y por ello únicamente presentamos un resumen de las principales aportaciones con el fin de contextualizar las contribuciones que se realizan en los capítulos de investigación 1, 2 y 4 de la tesis. En estos capítulos se analiza la relación que existe entre la obesidad y el sobrepeso y las características socio-económicas y socio-demográficas de la población (capítulo 1), el historial tabáquico (capítulo 2), y el consumo de CAP (capítulo 4).

Los capítulos 1 y 2 de la tesis utilizan muestras de población y bases de datos obtenidas a partir de las Encuestas Catalanas de Nutrición (ENCAT 1992-1993 y 2002-2003). Las características de estas encuestas no aparecen detalladas en esta sección introductoria, puesto que se han descrito ampliamente en numerosos artículos científicos publicados en revistas internacionales. Las publicaciones más relevantes sobre ENCAT se han citado en las secciones metodológicas de los capítulos 1 y 2.

Por otro lado, en esta sección se dedica una atención especial a describir la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012. Esta encuesta fue realizada en el marco del Proyecto europeo PlantLIBRA, en el que participó la

Fundación para la Investigación Nutricional-FIN. La encuesta fue dirigida por el Profesor Lluís Serra Majem y coordinada por la doctoranda. Los datos obtenidos han sido utilizados en esta tesis para analizar el consumo de complementos alimenticios a base de plantas (CAP) en 6 países de la Unión Europea (capítulo 3) y para analizar la relación entre el IMC y el uso de CAP (capítulo 4). El principal motivo para incluir una descripción detallada de la encuesta es que su elaboración es muy reciente y existen pocos artículos publicados que la hayan utilizado. También es importante señalar que hasta la fecha existe muy poca literatura que analice el consumo de CAP, su comercialización y el perfil de las personas que consumen este tipo de productos. Finalmente, se considera que la elaboración de la encuesta y la creación de esta base de datos constituyen una contribución metodológica importante de esta tesis.

Teniendo esto en cuenta, la sección 2.2 introduce diversos conceptos y definiciones utilizados en la preparación del material de la encuesta, describe la metodología empleada y explica las principales características de la base de datos. Por otro lado, también se describen los elementos relevantes del mercado de CAP, su regulación, la evolución que ha tenido la industria del control del peso corporal en los últimos años y la clasificación de los productos botánicos utilizados en el control/pérdida de peso.

1.1 Obesidad: exceso ponderal y adiposidad – una visión general

El sobrepeso y la obesidad se producen cuando el exceso de grasa se acumula en el cuerpo humano, lo que representa un riesgo para la salud. La obesidad es una enfermedad crónica multifactorial cuyos orígenes incluyen factores ambientales y genéticos (Serra-Majem & Bautista 2013; Varela-Moreira *et al.* 2013). Muchos de los casos de obesidad muestran un claro componente ambiental relacionado con el estilo de vida sedentario y hábitos dietéticos inadecuados que provocan un balance energético positivo y, como consecuencia, la acumulación gradual de tejido graso. Desde la perspectiva de la genética, se sabe actualmente que la obesidad es una enfermedad poligénica. Además, hay una comprensión incompleta de su fisiopatología, para lo cual es difícil discernir el papel de los diferentes polimorfismos y su interacción con factores ambientales (Serra-Majem & Bautista 2013).

La International Obesity Task Force (IOTF) y la Organización Mundial de la Salud (OMS) han declarado la obesidad como la epidemia del siglo XXI debido a las dimensiones adquiridas en las últimas décadas, su impacto en la morbi-mortalidad, la calidad de vida y los costes sanitarios relacionados. La OMS destaca el impacto que la obesidad tiene en el desarrollo de las enfermedades crónicas más prevalentes en nuestra sociedad: la diabetes tipo 2, las enfermedades cardiovasculares, las patologías musculo-esqueléticas y un número creciente de ciertos tipos de cáncer. El aumento del peso corporal también conduce a la aparición de depresión, alteración de la función cognitiva (Varela-Moreira *et al.* 2013) y trastornos relacionados con la imagen corporal, la autoestima, etc, resultando en interacciones sociales deterioradas (Serra-Majem & Bautista 2013). Por otra parte, genera importantes costes económicos directos e indirectos, así como aumentos significativos en los servicios sociales y de salud (visitas médicas, ausentismo, pérdida de autonomía, necesidades especiales, etc) (Serra-Majem & Bautista 2013; Varela-Moreira *et al.* 2013).

La prevención del exceso de peso corporal y de adiposidad es esencial, ya que una vez que un individuo alcanza el nivel de la obesidad, este se asocia a un alto grado de fracasos terapéuticos y a la tendencia a la recaída (Serra-Majem & Bautista 2013).

1.1.1 Medición del peso y la grasa corporales

Existen métodos directos e indirectos para medir el peso y la grasa corporales:

- Las medidas directas de la composición corporal proporcionan una estimación de la masa total de grasa corporal y varios componentes de la masa libre de grasa. Tales técnicas incluyen el peso bajo el agua, la resonancia magnética (MRI), la tomografía axial computarizada (TC o TAC) y la absorciometría dual de rayos X (DEXA). Los métodos se utilizan principalmente en investigación y en los centros de atención terciaria, pero se pueden utilizar como "métodos de referencia" ("gold standard") para validar las medidas antropométricas de la grasa corporal (Goran 1998).

- Las medidas indirectas se refieren a las medidas antropométricas de adiposidad relativa e incluyen, entre otras, medidas de la cintura, la cadera y otras medidas perimetrales, los pliegues cutáneos y los índices derivados de la altura y el peso medido como el índice de Quetelet (IMC o W H-2), el índice ponderal (W H-3) y fórmulas similares. Todas las mediciones antropométricas dependen en cierta medida de la habilidad de la persona que toma la medida, y su precisión debe ser validada en relación a una "medida de referencia" de la adiposidad (Lobstein, Raur & Uauy 2004).

1.1.2 Medidas de peso y grasa corporales utilizadas en esta tesis: Índice de Masa Corporal y Perímetro de la Cintura

Actualmente las definiciones de sobrepeso y obesidad se basan en el IMC y en el perímetro de la cintura (PC) (ICO 2010). Estas son las medidas que se han utilizado en la presente tesis. El IMC se define como el "peso en kilogramos dividido por el cuadrado de la altura en metros (kg/m^2). En esta investigación se ha seguido la clasificación internacional del bajo peso, del sobrepeso y de la obesidad en adultos según el IMC propuesta por la OMS (WHO 1998; WHO 2014: BMI). En cuanto al PC, los puntos de corte de la OMS de 1998 se han usado en el capítulo 1 y los de la OMS de 2008 y el riesgo de complicaciones metabólicas se han usado en el Capítulo 2 (WHO 2008).

1.1.3 Tasas y tendencias de la prevalencia de sobrepeso y obesidad en el ámbito mundial, Europeo y Español

- Datos mundiales

Las tasas de prevalencia del sobrepeso y la obesidad han aumentado en todo el mundo en las últimas 3 décadas. La OMS ha mostrado que las tasas mundiales de obesidad se han duplicado entre 1980 y 2003, llegando a más de 300 millones de personas obesas en 2003 (WHO 2003). Más recientemente, en su Observatorio Global de Salud (sus siglas en inglés son GHO, de "Global Health Observatory"), la OMS informó de que en 2008 en el mundo existían más de 500 millones de obesos adultos mayores de 20 años, es decir el 11% (WHO 2009). Estas cifras de la OMS concuerdan con las de la IASO/IOTF que se refiere a la obesidad como "la epidemia mundial", y cuyo reciente análisis (datos de 2010) estima que aproximadamente 475 millones de individuos son obesos. La IASO/IOTF añade que cuando se tienen en cuenta los puntos de corte específicos para asiáticos de la definición de obesidad (IMC>28 kg/m^2), el número de adultos considerados obesos a nivel mundial es de más de 600 millones (IASO/IOTF 2012).

Además, el GHO explica que la prevalencia de un índice de masa corporal elevado aumenta con el nivel de ingresos de los países; esto se produce hasta llegar a los países con los niveles de ingresos medios-altos (WHO 2009). En 2008, la prevalencia de la obesidad se triplicó, pasando del 7% de obesidad en ambos sexos en los países de ingresos medio-bajos hasta el 24% en los países de ingresos medios-altos. La obesidad entre las mujeres fue significativamente mayor que entre los hombres, a excepción de en los países de ingresos altos en los que fue similar. En los países de ingresos bajos y de ingresos medios-bajos la obesidad de las mujeres fue aproximadamente el doble que la de los hombres (WHO 2009). La obesidad, las dietas poco saludables y la poca actividad física a menudo están vinculadas entre sí y también a una serie de factores de riesgo son mucho más comunes entre las personas con ingresos bajos (WHO 2007).

Y el futuro no augura mejores expectativas. Según la OMS, en el año 2011, más de 40 millones de niños menores de cinco años tenían sobrepeso. El sobrepeso y la obesidad, que en el pasado fueron considerados un problema de los países de ingresos altos, van ahora en aumento en los países de ingresos bajos y medianos, especialmente en los entornos urbanos. Más de 30 millones de niños con sobrepeso viven en países en desarrollo y 10 millones en países desarrollados (WHO 2013). En 2018, se proyecta que más de 3 de cada 4 personas mayores de 15 años tendrán sobrepeso u obesidad en Kuwait, Venezuela y México, así como también en los EE.UU. (Euromonitor International 2014a).

- Datos Europeos

La OMS informó de una tasa de obesidad de aproximadamente el 22% de los adultos en el año 2008 en la Región Europea de la OMS (WHO 2009). La OMS ha publicado recientemente nueva información sobre las tasas de prevalencia de obesidad en adultos en 34 países europeos (OMS 2014): existen seis países con una tasa de prevalencia en el rango de 20 a 30%, con la Antigua República Yugoslava de Macedonia a la cabeza (aunque los datos no son directamente comparables).

Según la IASO/IOTF, en los 27 Estados Miembros de la UE, aproximadamente el 60% de los adultos y más del 20% de los niños en edad escolar tienen sobrepeso o son obesos. Esto equivale a alrededor de 260 millones de adultos y más de 12 millones de niños que son obesos o que tienen sobrepeso (IASO/IOTF 2014).

Utilizando los datos del Eurobarómetro 59.0 (Comisión Europea 2003), de Saint Pol (2009) publicó la media de IMC masculina y femenina en 15 países europeos, así como la distribución de la población por categorías de IMC en cada país (de Saint Pol de 2009). El Reino Unido tuvo la media de IMC femenina más alta, mientras que Grecia tuvo la media de IMC masculina más alta. De nuevo, Grecia y el Reino Unido tuvieron la mayor proporción de obesidad y sobrepeso.

- Datos Españoles

En España, varios estudios coinciden en señalar que la prevalencia de obesidad en adultos, adolescentes y niños ha aumentado en las últimas décadas (Serra-Majem *et al*. 2003; Aranceta-Bartrina *et al.* 2005). Las investigaciones publicadas muestran que el grupo de niños de edades comprendidas entre 6 y 13 años y el grupo de mujeres mayores de 45 años son los que tienen un mayor riesgo de obesidad; por otra parte, la prevalencia de obesidad es mayor en los hombres durante los años de crecimiento y desarrollo (Serra-Majem *et al*. 2003; Aranceta-Bartrina *et al.* 2005), mientras que en el grupo de mayores de 45 años es significativamente mayor en las mujeres (Gutiérrez-Fisac *et al.* 1994; Aranceta-Bartrina *et al.* 2005). En un estudio realizado en el sur de España, se encontró que la población masculina tenía una mayor proporción de sobrepeso que la femenina, aunque en el caso de la obesidad el resultado encontrado fue el opuesto (Mataix *et al.* 2005). En 2004, los resultados del Estudio DORICA (Aranceta *et al.* 2004) mostraron que la prevalencia de obesidad de la región noreste de España (que incluye Cataluña) era del 8,5% para los hombres y del 13,8% para las mujeres. Estas cifras de prevalencia eran las más bajas encontradas en las ocho regiones incluidas en el estudio (Aranceta-Bartrina *et al.* 2005).

Más recientemente, Gutiérrez-Fisac et al. (2011), utilizando datos del estudio ENRICA (Gutiérrez-Fisac *et al.* 2012), por primera vez presentó las tasas de prevalencia de obesidad general y abdominal del adulto español basadas en medidas del peso, la altura y el PC (utilizando criterios de la OMS 2008). Estos autores encontraron que la prevalencia de obesidad general era del 22,9% (24,4% en hombres y 21,4% en mujeres), y que alrededor del 36% de los adultos tenían obesidad abdominal (32% de los hombres y el 39% de las mujeres). Por otra parte, encontraron que la frecuencia de la obesidad general y abdominal aumentaba con la edad y afectaba al 35% y el 62% de las personas mayores de 65 años de edad, respectivamente. También señalaron que estas cifras disminuían al aumentar el nivel educativo (por ejemplo, el 29% de las mujeres con educación primaria o menos tenía obesidad frente a sólo el 11% de los que tenían estudios universitarios). En cuanto a la variación regional, observaron que la prevalencia de obesidad (ajustada por edad) era muy alta en las Islas Canarias y en el sur de España. En Cataluña, la prevalencia de obesidad general era ligeramente más alta en los hombres en comparación con las mujeres (21,8-24,8% frente a 20,1-23,4%), mientras que la tasa de obesidad abdominal era mucho más alta en las mujeres en comparación con los hombres (<25,5 frente a 34,8-8,9%) (Gutiérrez-Fisac *et al.* 2012).

1.1.4 Determinantes medioambientales del sobrepeso y la obesidad

Los factores medioambientales que determinan la obesidad se resumen en: factores socio-demográficos y socio-económicos (por ejemplo edad, sexo, nivel cultural, nivel socioeconómico y distribución geográfica), y factores relacionados con el estilo de vida (por ejemplo sedentarismo, dieta, dejar de fumar y de paridad).

1.1.5 Efectos sobre la salud del sobrepeso y la obesidad

De todas las consecuencias en la salud que tienen el sobrepeso y la obesidad (de acuerdo con informes de la OMS, entre otros), cabe destacar su impacto en los siguientes aspectos de la salud: las tasas de mortalidad, las enfermedades no transmisibles, la "doble carga" de la enfermedad, los costes de la asistencia sanitaria y la atención social, y la salud mental y la cultura.

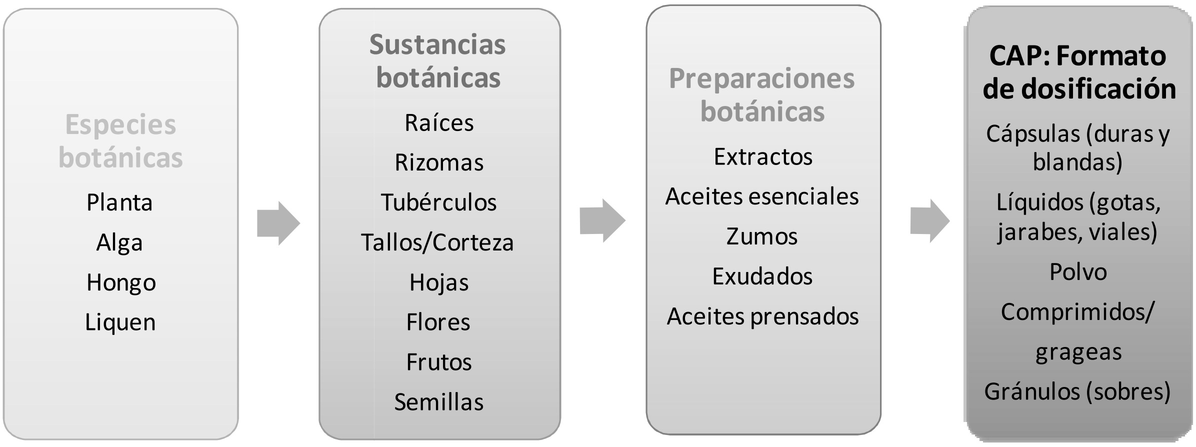
1.2. Complementos alimenticios a base de plantas (CAP) – aspectos relevantes

La popularidad de los productos botánicos va en aumento en Europa, y existe un gran número de personas que los utilizan para complementar sus dietas o para mantener la salud, por ejemplo, para el control del peso corporal. Estos productos se toman en muchos formatos diferentes, por ejemplo, como tés, zumos, productos medicinales a base de hierbas y CAP. Sin embargo, hay muy poca información a nivel europeo sobre cómo se están consumiendo estos productos, y este es el vacío que ha pretendido llenar la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012.

1.2.1 Conceptos y definiciones relevantes en la recogida de datos sobre el consumo de CAP

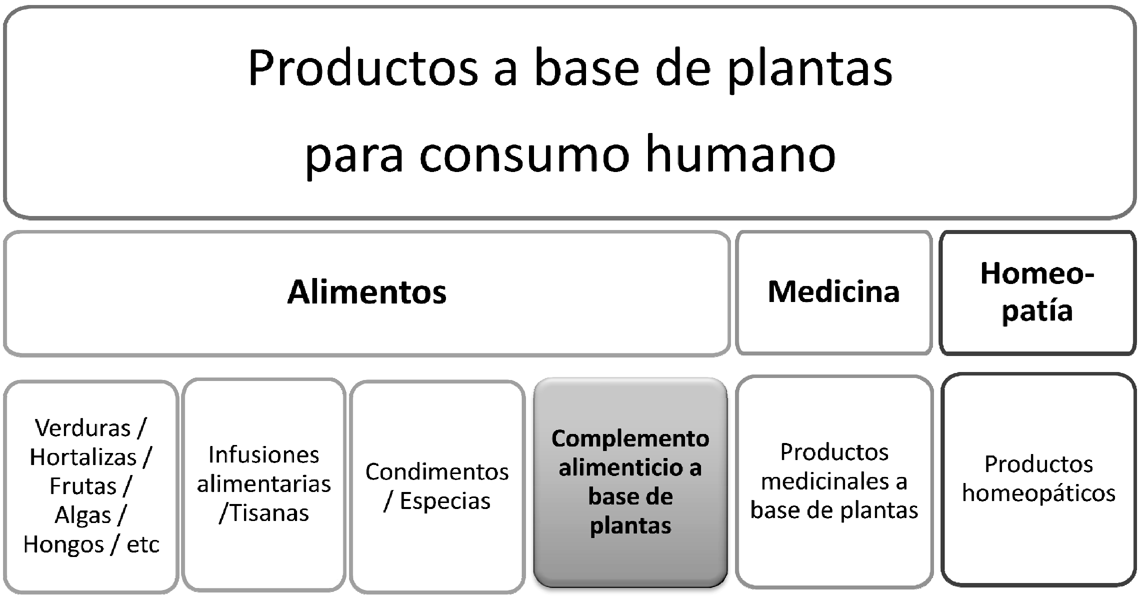
Al recoger datos sobre el consumo de CAP en una encuesta, es esencial tener todos los conceptos y definiciones pertinentes armonizados. Con el fin de proporcionar una idea general sobre la procedencia de los CAP, la Figura 1 muestra la ruta que las especies botánicas siguen hasta llegar al formato de dosificación de los CAP.

Figura 1. Desde la especie botánica hasta el CAP dosificado.



Las sustancias botánicas y los preparados botánicos se incluyen en diferentes productos, generalmente diseñados como productos a base de plantas para el consumo humano. Más tarde estos productos son clasificados como alimentos, medicamentos o productos homeopáticos (véase la Figura 2).

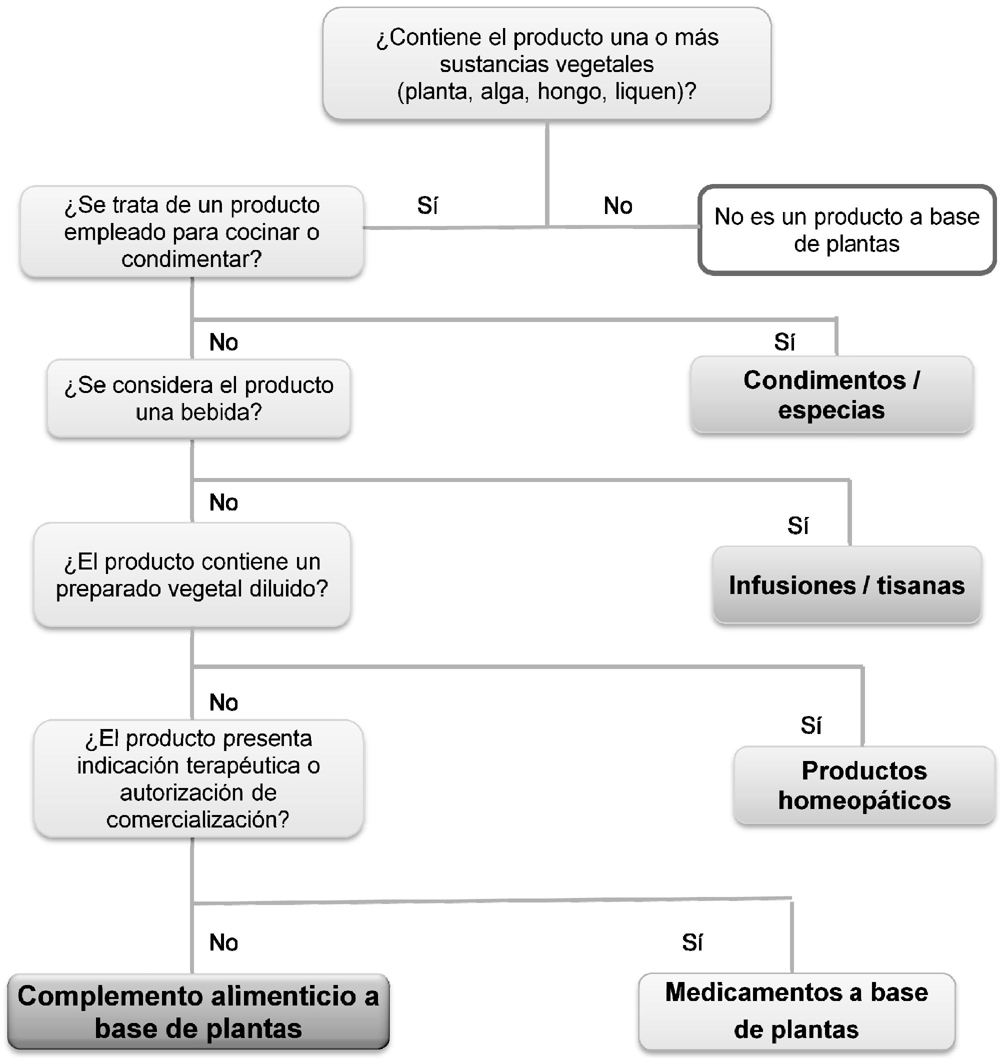
Figura 2. Clasificación de los productos a base de plantas.



Aunque existe una definición legal para los Complementos Alimenticios (Directiva de la UE (2002/46/CE) (European Parliament & Council 2002) en la que se incluyen los CAP, a efectos de esta investigación fue necesario desarrollar una definición específica de los CAP para este tipo de productos. Se considera que la principal característica de los CAP es que como es que como ingredientes contienen preparados botánicos que sirven para complementar los alimentos. En particular, la definición de CAP utilizada en la encuesta de los capítulos 3 y 4 fue la siguiente: “los CAP son productos alimenticios cuyo fin es complementar la dieta normal; son *fuentes concentradas de preparados botánicos* que tienen un efecto nutricional o fisiológico, solos o en combinación con vitaminas, minerales y otras sustancias. Los CAP son comercializados en formatos dosificados, tales como cápsulas, pastillas, tabletas, píldoras y otros formatos similares, sobrecitos de polvos, ampollas, botellas con cuentagotas y otros formatos similares de líquidos y polvos. Todos estos formatos están diseñados para tomar los productos en pequeñas cantidades unitarias".

Los CAP son productos muy específicos y no es fácil identificarlos en un mercado donde se comercializan muchos otros productos elaborados a base de plantas. Teniendo esto en cuenta, para capacitar a los entrevistadores durante el proceso de reclutamiento de los participantes de la encuesta se diseñó y utilizó el siguiente árbol de decisión (véase la Figura 3).

Figura 3. Árbol de decisión para identificar un complemento alimenticio a base de plantas.

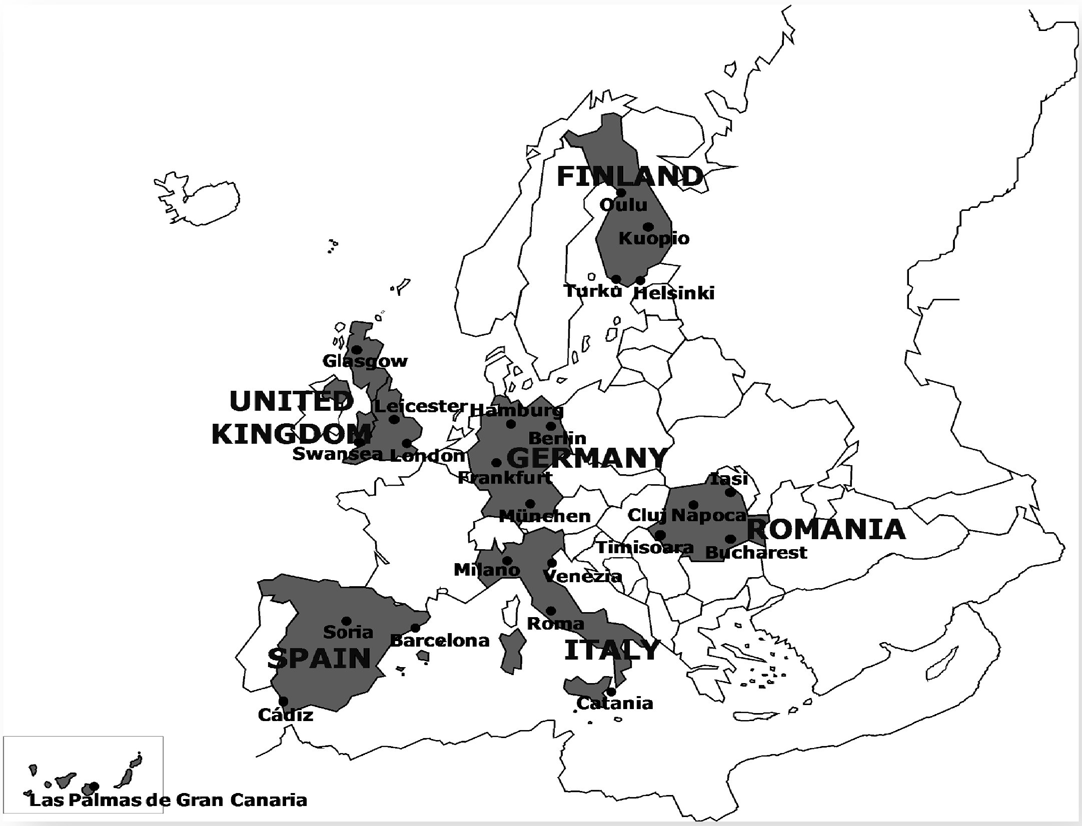


1.2.2 El projecto PlantLIBRA y la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012

PlantLIBRA (acrónimo de "PLANT Food Supplements: Levels of Intake, Benefit and Risk Assessment" - CONTRATO Nº 245199 de la CE) (www.plantlibra.eu/web) es un proyecto de investigación de cuatro años (2011-2014), cofinanciado por la CE en el contexto del Séptimo Programa Marco de la UE, que tuvo como objetivo fomentar el uso seguro de los complementos alimenticios que contienen plantas o preparados botánicos, mediante el aumento de la toma de decisiones basada en la evidencia por parte de los reguladores y los operadores de la cadena alimentaria. PlantLIBRA se llevó a cabo a través de un consorcio internacional de 25 socios y se organizó en 11 paquetes de trabajo (WP). El primer WP fue liderado por la FIN en Barcelona, y su actividad principal consistió en la realización de una encuesta para evaluar el consumo de CAP: la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012, que fue liderada por el director de esta tesis y coordinada por la doctoranda.

La Encuesta PlantLIBRA de Consumidores de CAP 2011-2012 es un estudio transversal realizado por 6 centros miembros de PlantLIBRA en cuyos países se llevó a cabo el trabajo de campo y la recogida de datos: Finlandia, Alemania, Italia, Rumania, España y el Reino Unido. El trabajo de campo duró más de 15 meses, desde mayo de 2011 hasta agosto de 2012. Los datos recogidos provenían de 2359 consumidores de CAP que residían en 24 ciudades europeas (4 por país) (véase la Figura 4). El trabajo de campo y recolección de datos fueron realizados por la empresa internacional de estudios de mercado EFG.

Figura 4. Países y ciudades que participan en la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012.



Se calculó una muestra estimada de cribado 2.000 personas por país con el fin de obtener una muestra final de aproximadamente 400 consumidores por país (N total=2.400 aproximadamente). Por país, las cuotas de género y grupo de edad se establecieron de la siguiente manera: 300 adultos (18 a 59 años) y 100 adultos mayores (a partir de 60 años), con un 30-50% de hombres y un 50-70% de mujeres. Todos los individuos fueron seleccionados por medio de un cuestionario de cribado de 5 minutos que registró el uso de CAP en los 12 meses anteriores a la entrevista (véase el Anexo II de esta tesis).

Aquellos individuos considerados "consumidores elegibles" (véase la Tabla 1) que también estaban dispuestos a participar en el estudio completaron durante una entrevista un cuestionario de 30 minutos sobre su uso de CAP. Este cuestionario constaba de 58 preguntas, 20 de las cuales preguntaban sobre aspectos del uso de

CAP y 38 sobre aspectos socio-demográficos, de salud y de estilo de vida (véase el Anexo III de esta tesis).

Tabla 1. Definición del consumidor “elegible” de CAP.

Los individuos eran consideraron elegibles para su inclusión en la encuesta si eran mayores de 18 años de edad y si cumplían alguno de los siguientes criterios específicos, destinados a captar los diferentes patrones de uso de los consumidores de CAP: 1) Habían tomado al menos 1 CAP en los últimos 12 meses, en un formato de dosis apropiado, con una frecuencia mínima de cualquiera de estas opciones: a) 1 dosis diaria durante al menos 2 semanas consecutivas o no consecutivas, o b) 1 o más dosis por semana durante un mínimo de 3 semanas consecutivas, o c) 1 o más dosis por semana durante al menos 4 semanas consecutivas o no consecutivas 2) Habían tomado 2 o más CAP diferentes, en un formato de dosificación adecuado, con una frecuencia mínima de 1 o más dosis por semana, y siendo la suma de la duración de uso de los 2 o más productos igual a por lo menos 4 semanas.

Los resultados del estudio han proporcionado datos para evaluar el perfil socio-demográfico de los usuarios de CAP, los patrones de uso de estos productos, los productos reales consumidos y sus ingredientes botánicos.

Los datos se organizaron en 3 bases de datos para su análisis: 1) la base de datos de "productos-ingredientes botánicos", 2) la base de datos del "consumidor", y 3) la base de datos resultante de la fusión de la de "consumidores y productos". Esto permitió la evaluación del consumo de CAP en la población seleccionada a tres niveles: a nivel ingrediente botánico, a nivel producto y a nivel consumidor.

Con el fin de validar el cuestionario de uso de CAP, se llevó a cabo un estudio de validación en el que los datos recogidos a través de la encuesta (cuestionario) se compararon con los datos recogidos con un diario de 30 a 180 días (utilizado como el “método de referencia”). El estudio se realizó en dos de las ciudades de la Encuesta de consumo PlantLIBRA: Las Palmas de Gran Canaria (España) y Milán (Italia), donde 48 y 49 consumidores respectivamente fueron reclutados mediante muestreo de conveniencia. El cuestionario de uso de CAP fue completado por los encuestados al principio y al final del período de 6 meses de la validación. Durante este tiempo los consumidores también completaron el diario de uso. Los datos de la última encuesta y el diario se compararon para evaluar la concordancia. Los resultados obtenidos mostraron una buena concordancia en cuanto al producto consumido, el formato de la dosis y las dosis por día.

1.2.3 Aspectos regulatorios de los CAP

Los complementos alimenticios (CA) están regulados por la Directiva 2002/46/CE, conocida como la Directiva sobre Complementos Alimenticios, que establece los requisitos que deben satisfacer este tipo de productos para su comercialización en la Comunidad (European Parliament & Council 2002). El objetivo de la Directiva era armonizar la legislación comunitaria en los Estados Miembros. Sin embargo, no tuvo en cuenta las sustancias distintas de las vitaminas y minerales, tales como aminoácidos y ácidos grasos, fibras, plantas y extractos de plantas, que se utilizan en la producción de los CA. Estas sustancias siguen siendo reguladas a través de diversos decretos nacionales que determinan su comercialización. Un problema de las legislaciones nacionales es que difieren ampliamente entre ellas. Algunos Estados Miembros han regulado el uso de productos botánicos en detalle, sobre la base de listas negativas de plantas no permitidas y/o listas positivas de las plantas permitidas. Algunos aplican condiciones específicas de uso (por ejemplo, niveles máximos, declaraciones de advertencia, etc) (Larrañaga–Guetaria 2012). Pero en la mayoría de los Estados Miembros, el fabricante o el distribuidor del producto tiene la obligación de notificar su actividad a las autoridades competentes mediante el envío de un modelo de la etiqueta utilizada. Este proceso es gratuito en algunos países europeos (Vargas-Murga *et al.* 2011). En algún caso, dicha información debe incluir los datos técnicos específicos sobre la composición y naturaleza del producto. Dicha información puede ser evaluada por los órganos nacionales específicos para consultas científicas (Larrañaga–Guetaria 2012).

A pesar de la multitud de normas nacionales, en la UE se aplica el principio básico Europeo “de reconocimiento mutuo”, por el que cualquier producto que se comercializa legalmente en un Estado Miembro puede ser comercializado en los 27 Estados Miembros. En la práctica, no obstante, este principio de reconocimiento mutuo no siempre se acepta y un Estado Miembro puede restringir las ventas de un producto de otro país en caso de considerar que existe un posible riesgo para la salud del consumidor. Cuando esto sucede, el Estado Miembro que no acepta el producto debe demostrar con pruebas el riesgo que supone el producto para la seguridad del consumidor. Desde 2008, el Reglamento 764/2008 establece procedimientos fijos a seguir en estos casos. Si un Estado Miembro se negase sistemáticamente a aplicar el reconocimiento mutuo, la CE podría iniciar procedimientos de infracción contra dicho Estado Miembro (Larrañaga–Guetaria 2012).

1.2.4 El mercado de los CAP

- Datos de mercado de los CAP en los Estados Miembros de la CE

Un estudio elaborado por European Advisory Services (EAS) proporciona datos detallados sobre los cuatro Estados Miembros de la CE que lideran las ventas de CAP: a la cabeza está Italia, seguida de cerca por Alemania, Reino Unido y Francia (EAS 2007). Según este estudio, el tamaño total estimado del mercado de los CA en la UE en 2005 era de unos 5 billones de euros (precios de venta al por menor). Los CA pueden dividirse entre aquellos que contienen vitaminas y minerales, que tenían una cuota de mercado del 50%, y los que contienen otras sustancias, que tienen una cuota de mercado del 43%, equivalente a 2,15 billones de euros. La mayor parte de las ventas de productos que contienen otras sustancias se realizaron en Alemania, Italia, Francia y el Reino Unido. El estudio mencionado también publicó que entre 1997 y 2005, el crecimiento del mercado de los CA que contienen otras sustancias osciló entre el 20% en el Reino Unido y un 219% en Polonia (EAS 2007; CE 2008).

Las proyecciones de crecimiento para los CA muestran una desaceleración para los próximos años. Esta situación podría responder a la modificación de algunos factores económicos, como por ejemplo la saturación del mercado. Otros factores que podrían afectar la comercialización de los CA que contienen otras sustancias son la notificación/autorización de los requerimientos y las restricciones nacionales a los canales de distribución, así como el grado en que las autoridades nacionales apliquen el reconocimiento mutuo (Vargas-Murga *et al.* 2011).

- Tendencias del mercado de los CAP

Una tendencia importante observada en el mercado es el paso del mercado de un solo ingrediente al mercado de múltiples ingredientes en tratamientos para una afección particular. También hay una mayor demanda de productos a base de plantas e ingredientes botánicos en fórmulas múltiples y en formato de paquetes combinados, así como de cápsulas masticables y tabletas. Los productos multi-hierbas/plantas constituyen el segmento más grande, capturando una parte significativa de los complementos a base de hierbas/plantas y del mercado mundial de remedios curativos. Se prevé que el crecimiento de este segmento de productos multi-hierbas/plantas superará el de otros mercados, ya que tuvo la tasa más rápida de crecimiento compuesto del 9,0% durante el período de análisis (2000-2006). También se espera que la soja y las hierbas/plantas especializadas muestren un fuerte potencial de crecimiento en el futuro (GIA 2011).

- Canales de distribución de los CAP

Las ventas directas por un lado y los canales de venta al consumidor o a los comerciantes minoristas por otro son las dos técnicas de marketing utilizadas por los fabricantes, distribuidores e importadores de CAP. Las ventas directas incluyen pedidos por correo, e-commerce, marketing multinivel y profesionales sanitarios médicos y de otras disciplinas alternativas. Las ventas a consumidores se concentran en las farmacias, tiendas naturistas de alimentación, herbolarios/herboristerías, para-farmacias, supermercados/hipermercados y locales/centros especializados (como gimnasios, peluquerías, centros de salud y belleza, tiendas de artículos deportivos) (Vargas-Murga *et al.* 2011).

Los canales de distribución al por menor más habituales en los Estados Miembros de UE son las farmacias, las tiendas naturistas, los herbolarios y los supermercados. La mayoría de los consumidores prefieren comprar CAP en herbolarios y farmacias donde pueden recibir asesoramiento sobre los beneficios del producto y la dosis (Vargas-Murga *et al.* 2011).

1.2.5 La industria del control del peso corporal: pasado, presente y futuro

El informe de la IOTF "Obesity in Europe 2002" mencionó que a finales de los años noventa en Europa hubo una enorme demanda de ayuda por parte de la población para perder peso. Se evidenció que la profesión médica no pudo o no supo responder a esta demanda. El resultado de esta situación fue el desarrollo de sistemas paralelos de ayuda, que incluyeron: a) grupos médicos no ortodoxos o privados que hacen afirmaciones sin fundamento de éxito, b) los clubes y grupos de adelgazamiento comerciales que cobran por las sesiones presenciales, c) empresas alimentarias y de otra índole que comercializan una amplia gama de "alimentos adelgazantes" o complementos dietéticos y coadyuvantes a la pérdida de peso selectiva, y d) un notable número de revistas que en muchas ocasiones ofrecen consejos contradictorios (IOTF 2002).

El informe de la IOTF también estimó que en 1995 el gasto total en la industria de adelgazamiento en la UE fue de al menos 15 billones de euros al año (y de alrededor de 1 billón de libras en el Reino Unido) (IOTF 2002). En España, el estudio prospectivo Delphi informó en 1999 de que un 80% de los españoles que querían perder peso gastó en promedio 60 euros al mes en todo tipo de tratamientos. El gasto total en productos de adelgazamiento ascendió a 2,05 billones de euros (Estudio prospectivo Delphi 1999).

Se ha calculado que en Estados Unidos en 2005 las ventas de complementos para perder peso ascendieron a más de 1,6 billones de dólares (Pillitteri *et al.* 2008; NBJ 2006); también se observó que entre 2011 y 2012 el mercado de los complementos alimenticios aumentó en un 7,5%, llegando a 32,5 billones de dólares en ventas (Euromonitor International 2014a).

Datos de Euromonitor International sobre el mercado global del control del peso en 2013 mostraron fuertes crecimientos anuales del 5%, alcanzando las ventas al por menor el valor de 14 billones de dólares. Euromonitor International afirmó que "si bien se preveía que el crecimiento continuaría hasta el 2018, con una “tasa compuesta de crecimiento anual” del 3%, los resultados variarían por región y tipo de producto" (Euromonitor 2014b).

1.2.6 Clasificación de los productos botánicos utilizados en la pérdida de peso

Los complementos para el control o la pérdida de peso normalmente se clasifican en las siguientes 4 categorías, en función de su mecanismo de acción hipotético para reducir el peso o cambiar la composición corporal (Manore 2012):

1) Los productos que bloquean la absorción de las grasas o de los hidratos de carbono, disminuyendo así la cantidad de energía absorbida de los alimentos (por ejemplo, el frijol común *(Phaseolus vulgaris*).
2) Los estimulantes que aumentan el metabolismo (por ejemplo, el té verde (*Camellia sinensis*).
3) Los productos que hipotéticamente alteran la partición de nutrientes, cambiando así la composición corporal al disminuir la grasa corporal y aumentar el tejido magro (por ejemplo, el tamarindo malabar *(Garcinia cambogia*).
4) Los productos que suprimen el apetito o aumentan la saciedad, resultando en una menor ingesta energética (por ejemplo, las fibras solubles tales como el glucomanano).

Muchos complementos que se usan en el control o la pérdida peso combinan varios ingredientes de estas categorías en un solo producto. Esto dificulta los tests de eficacia y seguridad (Manore 2012).

2. Investigación

Mi investigación se ha centrado en analizar el sobrepeso y la obesidad en adultos en relación a varios factores medioambientales. En particular, he analizado la importancia de los factores socioeconómicos (ocupación, educación), socio-demográficos (edad, sexo y tamaño de la población de residencia), y de estilo de vida (tabaquismo y consumo de CAP). He estudiado la relación entre el sobrepeso/obesidad y la ocupación, la educación, la edad, el género, el tamaño de la población de residencia y el historial tabáquico en la población catalana adulta, utilizando los datos de las dos Encuestas Catalanas de Nutrición (ENCATs 1992-93 y 2002-03), que son dos encuestas transversales metodológicamente idénticas. Además, he estudiado la relación entre el sobrepeso/obesidad y el consumo de CAP en la población adulta de 6 países de la UE donde se realizó la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012. Cada uno de los cuatro capítulos de investigación de esta tesis contiene su propia sección de Introducción, Metodología, Resultados y Discusión. A continuación se presenta un resumen de los objetivos, la metodología y los resultados de cada capítulo. Las conclusiones y las aportaciones originales de cada capítulo se explican posteriormente en la sección de Conclusiones de la tesis.

2.1 Capítulo 1: Tendencias de la obesidad y el sobrepeso en Cataluña, España (1992-2003), en relación al género y algunas variables socio-económicas[2]

2.1.1 Objetivos

Este estudio evalúa las tendencias de las tasas de prevalencia de obesidad y sobrepeso en la población adulta de Cataluña, España, en el período 1992-2003. También se evalúa la influencia que han tenido diversos factores socio-económicos en la evolución de estas tendencias.

2.1.2 Metodología

[2] Este trabajo de investigación fue publicado en la revista *Public Health Nutrition* (véase el Anexo IVa de esta tesis): García-Alvarez A, Serra-Majem L, Ribas-Barba L, Castell C, Foz M, Uauy R, Plasencia A, Salleras L. Obesity and overweight trends in Catalonia, Spain (1992-2003): gender and socio-economic determinants. *Public Health Nutr*. 2007 Nov;10(11A):1368-78.

Se analizaron datos de las dos Evaluaciones del Estado Nutricional en Cataluña (ENCAT 1992-1993 y ENCAT 2002-03), que son dos encuestas poblacionales representativas transversales. Los datos de peso y altura se obtuvieron mediante medición directa en condiciones estandarizadas por dietistas entrenados. El sobrepeso y la obesidad se definieron mediante el IMC y el PC, categorizados de acuerdo a criterios de la OMS de 1998. Las muestras globales consistieron en 1015 hombres y 1233 mujeres de ENCAT 1992-1993, y en 791 hombres y 924 mujeres de ENCAT 2002-03, todos de edades comprendidas entre 18 y 75 años.

2.1.3 Resultados

Para la elaboración de este resumen se han seleccionado solo algunos de los resultados más representativos del análisis.

En 2002-03 la media de IMC y la media de PC en hombres fueron más altas que en 1992-1993, mientras que para las mujeres la media de IMC fue más baja (excepto para el grupo de población más joven), y la media de PC fue más alta. La Tabla 2 muestra que en los hombres, la prevalencia del IMC de sobrepeso se mantuvo estable (pasó del 44,1% en 1992-1993 al 43,7% en 2002-2003), mientras que la del IMC de obesidad aumentó (pasó del 9,9% al 16,6%); por otro lado, el PC de sobrepeso total se mantuvo estable (de 21,7 a 23,8%), mientras que el de obesidad aumentó (de 13,1% a 24,4%). En las mujeres, el IMC de sobrepeso y el IMC de obesidad se mantuvieron estables (del 29,1% al 30,1% y del 15,0% al 15,2%, respectivamente); el PC de sobrepeso disminuyó (de 21,8% a 17,7%), mientras que el de obesidad aumentó (de 24,5% a 31,1%). Los factores socio-económicos y educativos tuvieron una influencia sobre las tasas de IMC y PC de sobrepeso y obesidad principalmente en mujeres en ambas encuestas y en los hombres más jóvenes en la encuesta de 1992-1993.

Tabla 2. La prevalencia del sobrepeso y la obesidad (por IMC y PC) según el género, el año de la encuesta (ENCAT 1992-93 y 2002-03), las características socio-económicas y las socio-demográficas.

	IMC de Sobrepeso[a]				IMC de Obesidad[b]				PC de Sobrepeso[c]				PC Obesidad[d]			
	Hombres		Mujeres		Hombres		Mujeres		Hombres		Mujeres		Hombres		Mujeres	
Variables	**1992-3**	**2002-3**	**1992-3**	**2002-3**	**1992-3**	**2002-3**	**1992-3**	**2002-3**	**1992-3**	**2002-3**	**1992-3**	**2002-3**	**1992-3**	**2002-3**	**1992-3**	**2002-3**
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Prevalencia total (cruda)[e]	44,1	43,7	29,1	30,1	9,9	16,6	15,0	15,2	21,7	23,8	21,8	17,7	13,1	24,4	24,5	31,1
Comparación inter-encuesta	*s**		*ns***		*s*		*ns*		*S*		*s*		*s*		*s*	
Edad (años)																
18-24	27,0	19,8	7,3	18,1	2,5	6,9	1,7	1,3	7,7	7,8	7,3	11,9	1,3	6,0	1,7	2,5
25-44	43,2	41,7	26,7	22,9	7,0	13,3	6,6	8,7	18,8	20,3	19,3	15,5	6,2	16,3	14,0	20,7
45-64	56,4	60,0	44,7	37,5	14,7	18,4	27,8	23,8	30,9	31,2	35,8	22,4	24,8	31,2	39,2	43,4
65-75	49,5	37,9	41,8	49,1	21,5	31,0	35,6	31,3	35,5	33,0	23,6	20,0	28,0	49,6	65,3	70,9
Comparación inter-encuesta	*s*		*ns*		*ns*		*ns*		*ns*		*ns*		*s*		*ns*	
Nivel socioeconómico (Ocupación)																
Bajo	44,7	44,0	28,6	33,3	11,0	16,5	23,4	19,9	23,5	23,5	23,3	19,0	11,4	25,8	32,0	39,0
Medio	44,8	45,0	30,7	28,2	10,2	16,4	13,3	11,2	22,2	25,1	23,1	16,5	14,2	21,5	22,9	26,0
Alto	43,0	42,6	25,7	25,2	8,3	16,5	5,8	11,2	18,6	21,9	17,8	17,1	13,3	26,3	15,3	19,3
Comparación intra-encuesta	*ns*	*ns*	*s*	*s*	*ns*	*ns*	*s*	*s*	*ns*	*ns*	*s*	*s*	*ns*	*ns*	*s*	*s*
Comparación inter-encuesta	*s*		*s*		*s*		*ns*		*s*		*s*		*s*		*s*	
Nivel educativo del sujeto																
Bajo	53,7	50,5	41,9	45,5	19,1	21,2	32,6	36,6	31,9	28,3	26,7	17,6	21,8	34,3	49,3	69,5
Medio	42,9	43,9	31,4	32,5	9,6	17,6	12,6	15,7	21,5	22,7	24,4	19,7	12,2	25,7	21,8	34,1
Alto	40,3	41,6	12,3	20,5	4,4	13,6	2,9	5,7	15,5	23,9	11,8	14,9	9,1	19,0	5,9	11,6
Comparación intra-encuesta	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*	*s*	*s*	*s*	*s*	*s*	*s*	*s*	*s*
Comparación inter-encuesta	*s*		*s*		*s*		*s*		*s*		*s*		*s*		*s*	
Nivel educativo del cabeza de familia																
Bajo	42,1	45,9	32,7	40,1	13,8	17,2	23,9	33,8	22,5	26,2	22,1	16,5	15,2	29,5	35,1	61,9
Medio	46,7	42,9	31,1	31,5	9,6	17,5	13,5	13,4	23,8	22,1	23,9	19,0	12,9	24,9	23,3	30,2
Alto	41,0	44,8	18,1	22,8	5,1	14,5	5,2	9,2	15,8	25,8	15,4	16,0	10,7	20,4	11,0	17,5
Comparación intra-encuesta	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*	*s*	*ns*	*s*	*s*
Comparación inter-encuesta	*s*		*s*		*s*		*s*		*s*		*s*		*s*		*s*	
Tamaño de la población (habitantes)																
<10.000	44,3	46,6	32,5	27,8	12,1	16,7	15,6	18,0	21,4	22,1	22,5	12,9	15,7	26,2	31,1	38,6
10.000-100.000	42,2	44,6	28,0	33,6	11,6	15,7	15,2	15,1	20,9	25,0	20,9	20,0	12,7	24,2	25,4	32,1
>100.000	45,0	41,8	28,9	28,8	8,6	17,1	14,8	13,8	22,1	23,7	22,0	18,4	12,6	23,7	22,7	26,8
Comparación intra-encuesta	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*ns*	*s*	*ns*	*ns*	*ns*	*s*
Comparación inter-encuesta	*ns*		*ns*		*ns*		*ns*		*ns*		*s*		*ns*		*s*	

s*: prueba de X^2 – diferencia significativa ($p \leq 0{,}05$).*ns*: prueba de X^2 – diferencia no-significativa. a. IMC 25-<30 kg/m^2; b. IMC$\geq$30 kg/m^2; c. PC 94-<102 cm para hombres y 80-<88 cm para mujeres; d. PC$\geq$102 cm para hombres y $\geq$ 88 cm para mujeres - (a-d) según clasificación de la OMS (WHO1998).

Capítulo 2: Tendencias en la asociación entre el historial tabáquico y la obesidad general/central en Cataluña (1992-2003), España[3]

2.2.1 Objetivos

Este estudio muestra las tendencias en la relación entre el historial tabáquico y el sobrepeso/obesidad general, y entre historial tabáquico y la adiposidad central, en adultos de la región mediterránea de Cataluña, España.

2.2.2 Metodología

Se utilizaron las dos encuestas ENCAT 1992-93 y 2002-03 ENCAT.. La muestra de ENCAT 1992-1993 consistió en 482 hombres y 589 mujeres y la de ENCAT 2002-03 en 515 hombres y 613 mujeres, todos de edades comprendidas entre 25 y 60 años. Dietistas entrenados tomaron las medidas antropométricas (peso, altura) y recogieron datos auto-informados sobre el hábito tabáquico, la dieta, el estilo de vida y el SES. Se utilizó el indicador de la OMS de 2008 de sobrepeso/obesidad general (IMC>=25) entre "nunca fumadores", exfumadores y fumadores actuales; se utilizó el indicador de la OMS de 2008 para estimar la adiposidad central entre personas que nunca habían fumado, exfumadores y fumadores actuales, incluyendo: el "riesgo aumentado de enfermedad metabólica por PC" (RA PC - con un PC de 94 a <102 cm en hombres y de 80 a <88 cm en mujeres) y el "riesgo aumentado substancialmente de enfermedad metabólica por PC" (RAS PC - con un PC >=102 cm en hombres y >=88 cm en mujeres). Las asociaciones multivariantes ajustadas se estimaron mediante regresión logística simple.

2.2.3 Resultados

Para la elaboración de este resumen se han seleccionado algunos de los resultados más representativos del análisis.

La prevalencia de sobrepeso/obesidad y de RA/RAS PC en hombres aumentó en 2002-2003 respecto de la encuesta anterior. Los exfumadores tenían la tasa

[3] Este trabajo de investigación ha sido enviado a una revista científica (véase el Anexo IVb de esta tesis).

de sobrepeso más alta (57,2%) y también el RAS PC (28,2%), pero los nunca-fumadores tenían la prevalencia de obesidad más alta (19,3%) y los fumadores-actuales la tasa más alta de RA PC (30,7%). En mujeres, después de 10 años, las diferencias observadas entre las tasas de prevalencia de los diferentes grupos de hábito tabáquico disminuyeron sustancialmente debido al aumento de las tasas combinadas en exfumadores y fumadores actuales, y a la disminución de las tasas combinadas en nunca-fumadores; las tasas de sobrepeso y RA PC más altas (32,2% y 21% respectivamente) se observaron en exfumadores, y las más altas de obesidad y RAS PC (16,5% y 33,2% respectivamente) en nunca-fumadores. Después de diez años, la mayoría de las asociaciones entre el historial tabáquico y la obesidad general y la central se vieron considerablemente atenuadas: únicamente el tabaquismo excesivo en hombres se mantuvo asociado con el RA/RAS PC (aunque la probabilidad pasó de ser tres veces más alta a ser dos veces más alta) y las fumadoras moderadas tenían 0,57 veces menos probabilidades de tener un RA/RAS PC ($p<0,10$) que las nunca fumadoras (véase la Tabla 3).

Tabla 3. Asociaciones entre el historial tabáquico y el IMC ≥25, y entre el historial tabáquico y el PC >94 cm (en hombres) y >80 cm (en mujeres).

Historial tabáquico	Sobrepreso/obesidad (BMI ≥25 kg/m²)				RA/RAS PC (PC>94 cm in men, PC>80 cm in women)			
	ENCAT 1992-93		ENCAT 2002-03		ENCAT 1992-93		ENCAT 2002-03	
	n	OR (IC 95%)	n	OR (IC 95%)	n	OR (IC 95%)	n	OR (IC 95%)
ASOCIACIONES AJUSTADAS POR EDAD								
Hombres	469		508		468		507	
Nunca fumador (ref)	74	1,0	121	1,0	37	1,0	95	1,0
Exfumador	68	1,23 (0,67-2,25)	88	0,98 (0,58-1,65)	50	**2,03*(1,08-3,81)**	70	0,94 (0,57-1,56)
Fumador leve (<=10cig/day)	48	1,23 (0,65-2,31)	40	0,72 (0,39-1,32)	22	0,94 (0,47-1,89)	29	0,67 (0,36-1,24)
Fumador moderado (11-20cig/day)	46	**0,47*(0,26-0,83)**	46	0,81 (0,45-1,46)	34	1,13 (0,60-2,10)	31	0,67 (0,38-1,17)
Fumador excesivo (>20cig/day)	24	0,61 (0,30-1,21)	31	1,22 (0,56-2,66)	24	**2,51*(1,22-5,14)**	29	**1,82‡(0,87-3,83)**
Mujeres	579		611		574		610	
Nunca fumador (ref)	187	1,0	151	1,0	195	1,0	174	1,0
Exfumador	20	**0,51*(0,27-0,98)**	58	1,02 (0,65-1,61)	22	**0,48*(0,25-0,91)**	66	0,94 (0,59-1,48)
Fumador leve (<=10cig/day)	24	**0,48*(0,26-0,89)**	34	1,01 (0,60-1,69)	23	**0,42*(0,22-0,78)**	41	0,95 (0,57-1,56)
Fumador moderado (11-20cig/day)	24	0,85 (0,42-1,75)	21	0,65 (0,35-1,22)	30	1,06 (0,54-2,12)	23	**0,53*(0,29-0,97)**
Fumador excesivo (>20cig/day)	8	1,09 (0,40-2,99)	6	**1,13*(2,18-4,33)**	6	0,84 (0,29-2,46)	7	1,09 (0,26-4,60)
ASOCIACIONES MULTIVARIANTES AJUSTADAS								
Hombres	443		503		442		502	
Nunca fumador (ref)		1,0		1,0		1,0		1,0
Exfumador		1,33 (0,69-2,54)[a]		0,97 (0,57-1,67)[c]		**2,37*(1,19-4,69)[b]**		1,01 (0,61-1,68)[d]
Fumador leve (<=10cig/day)		1,00 (0,52-1,93)[a]		0,73 (0,39-1,36)[c]		0,93 (0,46-1,92)[b]		0,71 (0,37-1,35)[d]
Fumador moderado (11-20cig/day)		**0,40*(0,22-0,75)[a]**		0,75 (0,41-1,36)[c]		1,12 (0,59-2,22)[b]		0,58 (0,32-1,04)[d]
Fumador excesivo (>20cig/day)		0,63 (0,31-1,29)[a]		1,11 (0,50-2,51)[c]		**2,73*(1,21-6,16)[b]**		**1,98‡(0,91-4,31)**[d]
Prueba de tendencia MH#		0,007		0,481		0,904		0,986
Mujeres	528		591		523		590	
Never (ref)		1,0		1,0		1,0		1,0
Former		0,71 (0,37-1,38)[a]		1,27 (0,78-2,05)[c]		**0,56‡(0,29-1,09)[b]**		1,14 (0,71-1,83)[d]
Current light (<=10cig/day)		**0,42*(0,22-0,81)[a]**		1,20 (0,67-2,13)[c]		**0,39*(0,20-0,77)[b]**		1,15 (0,68-1,93)[d]
Current moderate (11-20cig/day)		0,76 (0,36-1,60)[a]		0,71 (0,37-1,36)[c]		1,00 (0,49-2,05)[b]		**0,57‡(0,30-1,09)[d]**
Fumador excesivo (>20cig/day)		1.29(0.46-3.59)[a]		1.46(0.43-5.04)[c]		0.83(0.29-2.44)[b]		1.35(0.36-5.10)[d]
Prueba de tendencia MH#		0.000		0.046		0.006		0.025

OR= odds ratio, IC = intervalo de confianza. IMC= Índice de Masa Corporal; Sobrepeso= IMC 25-<30 kg/m²; obesidad= IMC≥30 kg/m²; sobrepeso/obesidad = individuos con sobrepeso más individuos con obesidad. PC= perímetro de la cintura; RA PC/RAS PC = individuos con RA PC más individuos con RAS PC; RA PC= Riesgo aumentado de complicaciones metabólicas (es decir, PC>94 cm en hombres, PC>80 cm en mujeres); RAS PC= Riesgo aumentado sustancialmente (es decir, PC>102 cm en hombres, PC>88 cm en mujeres); *p<0.05; ‡p<0.10. #MH=Mantel-Haenszel. a. Ajustado por edad, ingesta energética, nivel de actividad física en el trabajo, nivel educativo del sujeto y ocupación. b. Ajustado por edad, ingesta energética, nivel educativo del sujeto y consumo de fruta y verdura. c. Ajustado por edad, ingesta energética, nivel educativo del cabeza de familia, nivel educativo del sujeto, ocupación, consumo de fruta y verdura y consumo de alcohol. d. Ajustado por edad, ingesta energética, nivel educativo del sujeto, ocupación y consumo de alcohol.

2.3 Capítulo 3: Uso de complementos alimenticios a base de plantas en seis países europeos: resultados de la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012[4]

2.3.1 Objetivos

Este estudio pretende proporcionar una visión general de las características y los patrones de uso de las personas que consumen complementos alimenticios a base de plantas (CAP) en seis países europeos.

2.3.2 Metodología

Este estudio se llevó a cabo dentro del proyecto PlantLIBRA (FP7- proyecto financiado por la CE nº245199). Se recogieron datos sobre el uso de CAP en una encuesta transversal retrospectiva de consumidores de estos productos, utilizando un cuestionario de frecuencia de consumo/uso. Se seleccionó una muestra total de 2359 adultos (a partir de 18 años) consumidores de CAP residentes en Finlandia, Alemania, Italia, Rumania, España y el Reino Unido (n=400 por país aproximadamente). Se realizaron análisis descriptivos, con todos los datos estratificados por sexo, edad y país. Se presentaron frecuencias absolutas, porcentajes e intervalos de confianza del 95%.

2.3.3 Resultados

Para la elaboración de este resumen se han seleccionado solo algunas de las tablas de resultados más representativos. En general, se estima que el 18,8% de los encuestados seleccionados utiliza al menos un CAP (véase la Tabla 4). Las distintas características de los consumidores de CAP incluyeron: ser adulto mayor, tener un buen nivel de educación, no haber fumado nunca y tener una percepción de la propia salud “buena o muy buena'' (véanse Tablas 5 y 6). En el conjunto de todos los países, se identificaron 491 botánicos diferentes en los productos CAP consumidos (véase la Tabla 7). Los formatos de dosis más

[4] Este trabajo de investigación ha sido publicado en la revista *PLoS One* (véase el Anexo IVc de esta tesis): Garcia-Alvarez A, Egan B, de Klein S, Dima L, Maggi FM, et al. (2014) Usage of Plant Food Supplements across Six European Countries: Findings from the PlantLIBRA Consumer Survey. PLoS ONE 9(3): e92265. doi: 10.1371/journal.pone.0092265

populares fueron las cápsulas y las píldoras/tabletas (véase la Tabla 8). La mayoría de los consumidores utilizaron un solo producto y la mitad de todos los consumidores tomaron productos de un solo ingrediente botánico (no se muestran estos resultados). Los ingredientes botánicos consumidos con más frecuencia fueron *Ginkgo biloba* (ginkgo), *Oenothera biennis* (onagra) y *Cynara scolymus* (alcachofa) (véase la Tabla 9). Algunos resultados variaron entre países.

Table 4. Distribución de la muestra de los individuos cribados, de los consumidores de CAP entrevistados y de la prevalencia de consumo, por país y género.

			Finlandia	Alemania	Italia	Rumania	España	Reino Unido	Total
Contactos totales (n)	Total de individuos cribados para la encuesta	Hombres	1405	1031	907	795	811	830	5779
		Mujeres	1379	1028	1044	827	932	794	6004
	Total de entrevistas aceptadas de consumidores de CAP	Hombres	193	197	187	199	174	191	1141
		Mujeres	208	201	191	201	228	189	1218
Muestra de prevalencia: muestra seleccionada sistemáticamente en los 3 primeros meses del trabajo de campo (n)	Individuos cribados	Hombres	486	564	439	502	551	454	2996
		Mujeres	519	571	547	501	648	563	3349
	Consumidores de CAP entre los individuos cribados	Hombres	33	90	99	95	55	65	437
		Mujeres	71	111	156	124	133	144	739
Prevalencia de consumo de CAP (ponderada) (%)			9,6	16,9	22,7	17,6	18,0	19,1	18,8

Table 5. Encuesta PlantLIBRA de Consumidores de CAP – características socio-demográficas de la muestra, total y por país.

Características	Categorías	Todos los países		Finlandia		Alemania		Italia		Rumania		España		Reino Unido	
		n	% (IC 95 %)	n	% (CI 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)
Género	Hombres	1141	48,4 (46,4-50,4)	193	48,1 (43,2-53,0)	197	49,5 (44,6-54,4)	187	49,5 (44,4-54,5)	199	49,8 (44,8-54,7)	174	43,3 (38,4-48,1)	191	50,3 (45,2-55,3)
	Mujeres	1218	51,6 (49,6-53,7)	208	51,9 (47,0-56,8)	201	50,5 (45,6-55,4)	191	50,5 (45,5-55,6)	201	50,3 (45,3-55,2)	228	56,7 (51,9-61,6)	189	49,7 (44,7-54,8)
Edad	18-29 años	418	17,7 (16,2-19,3)	63	15,7 (12,1-19,3)	77	19,4 (15,5-23,2)	84	22,2 (18,0-26,4)	122	30,5 (26,0-35,0)	38	9,5 (6,6-12,3)	34	9,0 (6,1-11,8)
	30-39 años	445	18,9 (17,3-20,4)	65	16,2 (12,6-19,8)	57	14,3 (10,9-17,8)	88	23,3 (19,0-27,6)	65	16,3 (12,6-20,0)	101	25,1 (20,9-29,4)	69	18,2 (14,3-22,0)
	40-49 años	460	19,5 (17,9-21,1)	64	16,0 (12,4-19,6)	82	20,6 (16,6-24,6)	63	16,7 (12,9-20,4)	46	11,5 (8,4-14,6)	88	21,9 (17,8-25,9)	117	30,8 (26,1-35,4)
	50-59 años	441	18,7 (17,1-20,3)	105	26,2 (21,9-30,5)	80	20,1 (16,2-24,0)	49	13,0 (9,6-16,4)	67	16,8 (13,1-20,4)	76	18,9 (15,1-22,7)	64	16,8 (13,1-20,6)
	≥ 60 años	595	25,2 (23,5-27,0)	104	25,9 (21,6-30,2)	102	25,6 (21,3-29,9)	94	24,9 (20,5-29,2)	100	25,0 (20,8-29,3)	99	24,6 (20,4-28,8)	96	25,3 (20,9-29,6)
Educación	Bajo	249	10,6 (9,3-11,8)	47	11,7 (8,6-14,9)	3	0,8 (0,0-1,6)	72	19,1 (15,1-23,0)	35	8,8 (6,0-11,5)	92	22,9 (18,8-27,0)	0	-
	Medio	1549	65,7 (63,6-67,6)	237	59,1 (54,3-63,9)	329	82,7 (78,9-86,4)	222	58,7 (53,8-63,7)	190	47,5 (42,6-52,4)	256	63,7 (59,0-68,4)	315	82,9 (79,1-86,7)
	Alto	561	23,8 (22,1-25,5)	117	29,2 (24,7-33,6)	66	16,6 (12,9-20,2)	84	22,2 (18,0-26,4)	175	43,8 (38,9-48,6)	54	13,4 (10,1-16,8)	65	17,1 (13,3-20,9)
Estado actual de empleo	Con empleo	1357	57,5 (55,5-59,5)	204	50,9 (46,0-55,8)	240	60,3 (55,5-65,1)	221	58,5 (53,5-63,4)	249	62,3 (57,5-67,0)	244	60,7 (55,9-65,5)	199	52,4 (47,3-57,4)
	Otros grupos [a]	1002	42,5 (40,9-44,5)	197	49,1 (44,2-54,0)	158	39,7 (34,9-44,5)	157	41,5 (36,6-46,5)	151	37,8 (33,0-42,5)	181	39,3 (34,5-44,1)	181	47,6 (42,6-52,7)

[a]. Otros grupos: Sin empleo; Amas de casa; Estudiantes; Retirados; Incapacitados; y Otros.

Table 6. Encuesta PlantLIBRA de Consumidores de CAP – características de estilos de vida relacionados con la salud de la muestra, total y por país.

Características	Categorías	Todos los países		Finlandia		Alemania		Italia		Rumania		España		Reino Unido	
		n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)	n	% (IC 95 %)
Uso regular de CA no CAP[ab]	No	1536	65,1 (63,2-67,0)	83	20,7 (16,7-24,7)	251	63,1 (58,3-67,8)	311	82,3 (78,4-86,1)	274	68,5 (63,9-73,1)	312	77,6 (73,5-81,7)	305	80,3 (76,3-84,3)
	Sí	767	32,5 (30,6-34,4)	306	76,3 (72,1-80,5)	122	30,7 (26,1-35,2)	63	16,7 (12,9-20,4)	112	28,0 (23,6-32,4)	89	22,1 (18,1-26,2)	75	19,7 (15,7-23,7)
	No estoy seguro	56	2,4 (1,8-3,0)	12	3,0 (1,3-4,7)	25	6,3 (3,9-8,7)	4	1,1 (0,1-2,1)	14	3,5 (1,7-5,3)	1	0,3 (0,0-0,7)	0	-
Hábito tabáquico	Nunca fumador	1100	46,6 (44,6-48,6)	182	45,4 (40,5-50,3)	183	46,0 (41,1-50,9)	181	47,9 (42,8-52,9)	214	53,5 (48,6-58,4)	177	44,0 (39,2-48,9)	163	42,9 (37,9-47,9)
	Exfumador	544	23,1 (21,4-24,8)	129	32,2 (27,6-36,8)	81	20,4 (16,4-24,3)	85	22,5 (18,3-26,7)	57	14,3 (10,8-17,7)	94	23,4 (19,2-27,5)	98	25,8 (21,4-30,2)
	Fumador actual	715	30,3 (28,5-32,2)	90	22,4 (18,4-26,5)	134	33,7 (29,0-38,3)	112	29,6 (25,0-34,2)	129	32,3 (27,7-36,8)	131	32,6 (28,0-37,2)	119	31,3 (26,7-36,0)
Percepción del estado de salud	Muy Buena	353	15,0 (13,5-16,4)	81	20,2 (16,3-24,1)	49	12,3 (9,1-15,5)	22	5,8 (3,5-8,2)	80	20,0 (16,1-23,9)	49	12,2 (9,0-15,4)	72	19,0 (15,0-22,9)
	Buena	1427	60,5 (58,5-62,5)	225	56,1 (51,3-61,0)	220	55,3 (50,4-60,2)	243	64,3 (59,5-69,1)	245	61,3 (56,5-66,0)	258	64,2 (59,5-68,9)	236	62,1 (57,2-67,0)
	Ni buena ni mala	496	21,0 (19,4-22,7)	77	19,2 (15,3-23,1)	111	27,9 (23,5-32,3)	111	29,4 (24,8-34,0)	73	18,3 (14,5-22,0)	81	20,2 (16,2-24,1)	43	11,3 (8,1-14,5)
	Mala	70	3,0 (2,3-3,7)	16	4,0 (2,1-5,9)	18	4,5 (2,5-6,6)	2	0,5 (0,0-1,3)	2	0,5 (0,0-1,2)	14	3,5 (1,7-5,3)	18	4,7 (2,6-6,9)
	Muy mala	13	0,6 (0,3-0,9)	2	0,5 (0,0 - 1,2)	0	-	0	-	0	-	0	-	11	2,9 (1,2-4,6)
Uso de MCA[c]	Sí	947	40,1 (38,2-42,1)	223	55,6 (50,7-60,5)	204	51,3 (46,3-56,2)	96	25,4 (21,0-29,8)	77	19,3 (15,4-23,1)	319	79,4 (75,4-83,3)	28	7,4 (4,7-10,0)
	No	1412	59,9 (57,9-61,8)	178	44,4 (39,5-49,3)	194	48,7 (43,8-53,7)	282	74,6 (70,2-79,0)	323	80,8 (76,9-84,6)	83	20,7 (16,7-24,6)	352	92,6 (90,0-95,3)
Consumo de alcohol	0-<1 veces/día	1398	59,3 (57,3-61,3)	281	70,1 (65,6-74,6)	245	61,6 (56,8-66,3)	116	30,7 (26,0-35,3)	232	58,0 (53,2-62,8)	291	72,4 (68,0-76,8)	233	61,3 (56,4-66,2)
	≥ 1 veces/día	296	12,6 (11,2-13,9)	13	3,2 (1,5-5,0)	27	6,8 (4,3-9,3)	156	41,3 (36,3-46,2)	9	2,3 (0,8-3,7)	46	11,4 (8,3-14,6)	45	11,8 (8,6-15,1)
	No estoy seguro	614	26,0 (24,3-27,8)	107	26,7 (22,4-31,0)	126	31,7 (27,1-36,2)	106	28,0 (23,5-32,6)	159	39,8 (35,0-44,6)	65	16,2 (12,6-19,8)	102	26,8 (22,4-31,3)
Categorías de IMC[d]	Bajo peso	69	2,9 (2,4-3,6)	9	2,2 (0,8-3,7)	4	1,0 (0,0-2,0)	12	3,2 (1,4-4,9)	20	5,0 (2,9-7,1)	6	1,5 (,3-2,7)	18	4,7 (2,6-6,9)
	Normopeso	1116	47,3 (45,3-49,3)	188	46,9 (42,0-51,8)	198	49,7 (44,8-54,7)	246	65,1 (60,3-69,9)	184	46,0 (41,1-50,9)	169	42,0 (37,2-46,9)	131	34,5 (29,7-39,3)
	Sobrepeso	818	34,7 (32,8-36,6)	147	36,7 (31,9-41,4)	159	40,0 (35,1-44,8)	98	25,9 (21,5-30,4)	142	35,5 (30,8-40,2)	155	38,6 (33,8-43,3)	117	30,8 (26,1-35,4)
	Obesidad	356	15,1 (13,7-16,5)	57	14,2 (10,8-17,6)	37	9,3 (6,4-12,2)	22	5,8 (3,5-8,2)	54	13,5 (10,2-16,9)	72	17,9 (14,2-21,7)	114	30,0 (25,4-34,6)
Nivel de actividad física[e]	Bajo	436	18,5 (16,9-20,1)	53	13,2 (9,9-16,5)	87	21,9 (17,8-25,9)	141	37,3 (32,4-42,2)	5	1,3 (0,2-2,3)	43	10,7 (7,7-13,7)	107	28,2 (23,6-32,7)
	Moderado	909	38,5 (36,6-40,5)	156	38,9 (34,1-43,7)	139	34,9 (30,2-39,6)	191	50,5 (45,5-55,6)	53	13,3 (9,9-16,6)	234	58,2 (53,4-63,0)	136	35,8 (31,0-40,6)
	Alto	1012	42,9 (40,9-44,9)	192	47,9 (43,0-52,8)	171	43,0 (38,1-47,8)	45	11,9 (8,6-15,2)	342	85,5 (82,1-89,0)	125	31,1 (26,6-35,6)	137	36,1 (31,2-40,9)

[a] Pregunta de la encuesta***:*** Además de COMPLEMENTOS ALIMENTICIOS A BASE DE PLANTAS, has tomado alguno de los siguientes complementos de forma regular en los últimos 12 meses? (marcar todos los que correspondan). ***Respuestas posibles:*** Vitaminas (A, B, D, E, etc.); Minerales (por ej. potasio, calcio); Amino ácidos; Enzimas (por ej. lactasa); Prebióticos (por ej. oligosacáridos, fibra); Probióticos (por ej. bífidobacteria, levaduras); Ácidos grasos (por ej. Aceite de pescado); Otros.

[b] CA= Complemento alimenticio.

[c] MCA=Medicina Complementaria y Alternativa, incluyendo : Acupunturista; Quiropráctico; Homeópata; Herbalista; Terapeuta de masaje; Curandero; Reflexólogo; Tratamiento reconocido, es decir, no "alternativo";Tratamiento esotérico; y "No se puede clasificar".

[d] IMC= Índice de Masa Corporal; Categorías de la OMS (WHO 2013).

[e] Categorías del IPAQ (Craig *et al.* 2003).

Table 7. Encuesta PlantLIBRA de Consumidores de CAP – Características de los CAP según las respuestas de los participantes.

	Total	Finlandia	Alemania	Italia	Rumania	España	Reino Unido
Número de productos	1288	213	190	289	196	284	116
Número de ingredientes botánicos	491	196	191	222	219	218	47
Número de fabricantes-productores	449	69	99	106	61	97	17
Número máximo de ingredientes por producto	46	23	46	20	39	30	8

Table 8. Encuesta PlantLIBRA de Consumidores de CAP – formatos de dosis de CAP utilizados, por producto usado por participante, total y por sexo y grupo de edad.

Formato de dosis	Total		Género				Grupo de edad			
	(n=2874)		Hombres (n=1358)		Mujeres (n=1516)		18-59 años (n=2131)		≥60 años (n=743)	
	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)	n	% (95 % CI)
Cápsulas[a]	1101	38,3 (36,5-40,1)	522	38,4 (35,9-41,0)	579	38,2 (35,8-40,6)	844	39,6 (37,5-41,7)	257	34,6 (31,2-38,0)
Píldoras/pastillas/grageas	1057	36,8 (35,0-38,5)	498	36,7 (34,1-39,2)	559	36,9 (34,4-39,3)	765	35,9 (33,8-37,9)	292	39,3 (35,8-42,8)
Líquidos[b]	513	17,9 (16,5-19,3)	238	17,5 (15,5-19,6)	275	18,1 (16,2-20,1)	374	17,6 (15,9-19,2)	139	18,7 (15,9-21,5)
Ampollas	104	3,6 (2,9-4,3)	53	3,9 (2,9-4,9)	51	3,4 (2,5-4,3)	75	3,5 (2,7-4,3)	29	3,9 (2,5-5,3)
Otros[c]	99	3,4 (2,8-4,1)	47	3,5 (2,5-4,4)	52	3,4 (2,5-4,4)	73	3,4 (2,7-4,2)	26	3,5 (2,2-4,8)

Pregunta de la encuesta. Y ¿en qué forma sueles tomarlo? (marca el formato que corresponda). *Posibles respuestas*: Píldoras/pastillas/grageas; Cápsulas/perlas de gel blando; Cápsulas duras; Líquidos (extracto/jarabe/gotas); Sobres/paquetes; Ampollas; Otros (especificar); No estoy seguro.

[a].Cápsulas: capsules/perlas/cápsulas duras

[b].Líquidos: extractos/jarabes/gotas

[c].Otros: Polvos, sobres/paquetes, barritas y “no estoy seguro”.

Table 9. Encuesta PlantLIBRA de Consumidores de CAP – distribución de los 40 ingredientes botánicos más consumidos y su clasificación general y estratificada por sexo y grupo de edad.

Ingredientes botánicos	Todos los consumidores			Género Hombres			Mujeres			Grupo de edad 18-59 años			≥60 años		
	Posición[a]	n	% (95 % CI)	Posición[b]	n	% (95 % CI)	Posición[b]	n	% (95 % CI)	Posición[b]	n	% (95 % CI)	Posición[b]	n	% (95 % CI)
Ginkgo biloba	1	194	8,2 (7,1-9,3)	1	107	9,4 (7,7-11,0)	3	87	7,1 (5,7-8,6)	2	135	7,7 (6,4-8,9)	1	59	9,9 (7,5-12,3)
Oenothera biennis	2	194	8,2 (7,1-9,3)	3	85	7,5 (5,9-8,9)	1	109	9,0 (7,4-10,5)	1	145	8,2 (6,9-9,5)	2	49	8,2 (6,0-10,4)
Cynara scolymus	3	173	7,3 (6,3-8,4)	5	73	6,4 (5,0-7,8)	2	100	8,2 (6,7-9,7)	4	128	7,3 (6,1-8,4)	4	45	7,6 (5,4-9,6)
Panax ginseng	4	167	7,1 (6,0-8,1)	2	94	8,2 (6,6-9,8)	5	73	6,0 (4,7-7,3)	3	133	7,5 (6,3-8,7)	6	34	5,7 (3,9-7,5)
Aloe vera	5	145	6,2 (5,2-7,1)	4	80	7,0 (5,5-8,5)	7	65	5,3 (4,1-6,6)	5	99	5,6 (4,5-6,7)	3	46	7,7 (5,6-9,8)
Foeniculum vulgare ssp.	6	132	5,6 (4,7-6,5)	7	59	5,2 (3,9-6,4)	4	73	6,0 (4,7-7,3)	6	99	5,6 (4,5-6,7)	7	33	5,6 (3,7-7,3)
Valeriana officinalis	7	125	5,3 (4,4-6,2)	6	62	5,4 (4,1-6,7)	8	63	5,2 (3,9-6,4)	7	97	5,5 (4,4-6,5)	9	28	4,7 (3,0-6,4
Glycine max	8	103	4,4 (3,5-5,2)	24	34	3,0 (2,0-3,9)	6	69	5,7 (4,4-6,9)	10	81	4,6 (3,6-5,5)	14	22	3,7 (2,2-5,2)
Melissa officinalis	9	103	4,4 (3,5-5,2)	8	53	4,7 (3,4-5,8)	10	50	4,1 (3,0-5,2)	9	82	4,7 (3,7-5,6)	17	21	3,5 (2,1-5,0)
Echinacea purpurea	10	102	4,3 (3,5-5,1)	12	43	3,8 (2,7-4,8)	9	59	4,8 (3,6-6,0)	8	83	4,7 (3,7-5,7)	21	19	3,2 (1,8-4,6)
Vaccinium myrtillus	11	100	4,2 (3,4-5,1)	9	53	4,7 (3,4-5,8)	13	47	3,9 (2,8-4,9)	12	71	4,0 (3,1-4,9)	8	29	4,9 (3,1-6,6)
Pimpinella anisum	12	89	3,8 (3,0-4,5)	11	47	4,1 (3,0-5,2)	21	42	3,5 (2,4-4,4)	16	65	3,7 (2,8-4,5)	11	24	4,0 (2,5-5,6)
Zingiber officinale	13	89	3,8 (3,0-4,5)	10	53	4,7 (3,4-5,8)	29	36	3,0 (2,0-3,9)	15	66	3,7 (2,9-4,6)	13	23	3,9 (2,3-5,4)
Camellia sinensis	14	87	3,7 (2,9-4,5)	17	39	3,4 (2,4-4,4)	11	48	3,9 (2,9-5,0)	11	72	4,1 (3,2-5,0)	33	15	2,5 (1,3-3,7)
Vitis vinifera	15	87	3,7 (2,9-4,5)	16	41	3,6 (2,5-4,6)	15	46	3,8 (2,7-4,8)	13	71	4,0 (3,1-4,9)	32	16	2,7 (1,4-4,0)
Taraxacum officinale	16	80	3,4 (2,7-4,1)	21	36	3,2 (2,1-4,1)	17	44	3,6 (2,6-4,6)	17	65	3,7 (2,8-4,5)	34	15	2,5 (1,3-3,7)
Echinacea angustifolia	17	79	3,4 (2,6-4,1)	23	34	3,0 (2,0-3,9)	16	45	3,7 (2,6-4,7)	20	60	3,4 (2,6-4,2)	20	19	3,2 (1,8-4,6)
Passiflora incarnata	18	78	3,3 (2,6-4,0)	30	30	2,6 (1,7-3,5)	12	48	3,9 (2,9-5,0)	19	61	3,5 (2,6-4,3)	30	17	2,9 (1,5-4,2)
Linum usitatissimum	19	77	3,3 (2,6-4,0)	13	43	3,8 (2,7-4,8)	33	34	2,8 (1,9-3,7)	22	56	3,2 (2,4-4,0)	16	21	3,5 (2,1-5,0)
Equisetum arvense	20	76	3,2 (2,5-3,9)	19	37	3,2 (2,2-4,2)	23	39	3,2 (2,2-4,2)	23	55	3,1 (2,3-3,9)	15	21	3,5 (2,1-5,0)
Allium sativum	21	75	3,2 (2,5-3,9)	28	32	2,8 (1,9-3,7)	18	43	3,5 (2,5-4,5)	29	50	2,8 (2,1-3,6)	10	25	4,2 (2,6-5,8)
Harpagophytum procumbens	22	75	3,2 (2,5-3,9)	18	39	3,4 (2,4-4,4)	26	36	3,0 (2,0-3,9)	40	40	2,3 (1,6-2,9)	5	35	5,9 (4,0-7,7)
Olea europaea	23	75	3,2 (2,5-3,9)	27	33	2,9 (1,9-3,8)	20	42	3,5 (2,4-4,4)	24	55	3,1 (2,3-3,9)	19	20	3,4 (1,9-4,8)
Glycyrrhiza glabra	24	74	3,1 (2,4-3,8)	26	33	2,9 (1,9-3,8)	22	41	3,4 (2,4-4,4)	25	54	3,1 (2,3-3,8)	18	20	3,4 (1,9-4,8)
Mentha piperita	25	72	3,1 (2,4-3,8)	20	36	3,2 (2,1-4,1)	27	36	3,0 (2,0-3,9)	27	53	3,0 (2,2-3,8)	22	19	3,2 (1,8-4,6)
Paullinia cupana	26	72	3,1 (2,4-3,8)	14	43	3,8 (2,7-4,8)	38	29	2,4 (1,5-3,2)	14	66	3,7 (2,9-4,6)	74	6	1,0 (0,2-1,8)
Malpighia glabra	27	71	3,0 (2,3-3,7)	15	41	3,6 (2,5-4,6)	37	30	2,5 (1,6-3,3)	18	61	3,5 (2,6-4,3)	51	10	1,7 (0,7-2,7)
Oenothera spec	28	70	3,0 (2,3-3,7)	41	23	2,0 (1,2-2,8)	14	47	3,9 (2,8-4,9)	21	59	3,3 (2,5-4,2)	47	11	1,9 (0,8-2,9)
Silybum marianum	29	69	2,9 (2,2-3,6)	25	34	3,0 (2,0-3,9)	30	35	2,9 (1,9-3,8)	32	46	2,6 (1,9-3,3)	12	23	3,9 (2,3-5,4)
Matricaria chamomilla	30	67	2,8 (2,2-3,5)	34	29	2,5 (1,6-3,4)	25	38	3,1 (2,1-4,1)	26	54	3,1 (2,3-3,8)	38	13	2,2 (1,0-3,3)
Citrus limon	31	66	2,8 (2,1-3,5)	37	24	2,1 (1,3-2,9)	19	42	3,5 (2,4-4,4)	30	48	2,7 (2,0-3,5)	25	18	3,0 (1,7-4,4)
Urtica dioica	32	64	2,7 (2,1-3,4)	31	30	2,6 (1,7-3,5)	34	34	2,8 (1,9-3,7)	28	51	2,9 (2,1-3,7)	37	13	2,2 (1,0-3,3)
Thymus vulgaris	33	63	2,7 (2,0-3,3)	36	28	2,5 (1,6-3,3)	31	35	2,9 (1,9-3,8)	33	44	2,5 (1,8-3,2)	24	19	3,2 (1,8-4,6)
Salvia officinalis	34	61	2,6 (2,0-3,2)	32	22	1,9 (1,1-2,7)	35	39	3,2 (2,2-4,2)	34	43	2,4 (1,7-3,1)	29	18	3,0 (1,7-4,4)
Cassia senna	35	60	2,5 (1,9-3,2)	43	29	2,5 (1,6-3,4)	24	31	2,6 (1,7-3,4)	37	43	2,4 (1,7-3,1)	28	17	2,9 (1,5-4,2)
Rosmarinus officinalis	36	60	2,5 (1,9-3,2)	38	24	2,1 (1,3-2,9)	28	36	3,0 (2,0-3,9)	39	41	2,3 (1,6-3,0)	23	19	3,2 (1,8-4,6)
Carum carvi	37	59	2,5 (1,9-3,1)	22	35	3,1 (2,1-4,0)	43	24	2,0 (1,2-2,7)	31	46	2,6 (1,9-3,3)	36	13	2,2 (1,0-3,3)
Hypericum perforatum	38	59	2,5 (1,9-3,1)	29	31	2,7 (1,8-3,6)	39	28	2,3 (1,5-3,1)	35	43	2,4 (1,7-3,1)	31	16	2,7 (1,4-4,0)
Lavandula angustifolia	39	57	2,4 (1,8-3,0)	40	23	2,0 (1,2-2,8)	32	34	2,8 (1,9-3,7)	36	43	2,4 (1,7-3,1)	35	14	2,4 (1,1-3,5)
Ribes nigrum	40	53	2,3 (1,7-2,8)	42	22	1,9 (1,1-2,7)	36	31	2,6 (1,7-3,4)	38	41	2,3 (1,6-3,0)	41	12	2,0 (0,9-3,1)

[a] Productos ordenados de acuerdo a la distribución general de los consumidores de los 40 ingredientes botánicos más utilizados (ranking no ponderado).

[b] Las posiciones muestran los cambios de los productos botánicos en la posición del ranking de 1-40 no ponderado general al estratificarlo por sexo y grupo de edad.

2.4 Capítulo 4: IMC de sobrepeso y obesidad en relación al uso de complementos alimenticios a base de plantas en seis países europeos: resultados de la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012

2.4.1 Objetivos

Este estudio pretende identificar los ingredientes botánicos de los CAP consumidos por "razones de peso corporal" y por "personas que hacen dieta para reducir el sobrepeso/obesidad" en seis países europeos. Por otro lado, pretende analizar la relación entre el consumo de estos ingredientes botánicos identificados y el IMC auto-informado de sus consumidores.

2.4.2 Metodología

Los datos utilizados provienen de la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012, una encuesta transversal retrospectiva de 2359 consumidores de CAP que utiliza un cuestionario de frecuencia de consumo de CAP. Los análisis se realizaron en dos submuestras de consumidores que 1) consumen los productos por "razones de peso corporal" y 2) que hacen "dieta contra el sobrepeso/obesidad"; en cada submuestra se presentaron las proporciones por país. Se identificaron los ingredientes botánicos de los CAP consumidos por los encuestados que responden "por razones de peso corporal", los consumidos por personas que hacen "dieta de sobrepeso/obesidad" y los consumidos por los que pertenecen a la "tabulación cruzada de los dos grupos". La relación entre los 5 botánicos más consumidos y el IMC auto-informado en el grupo 1 y 2 se exploró mediante la comparación de proporciones del IMC de los consumidores frente a los no consumidores (utilizando la prueba χ^2, y $p<0,05$ para la significación). Las comparaciones se realizaron usando a) la muestra de consumidores por "razón de peso corporal" (n=240) y la muestra de consumidores que están "a dieta de sobrepeso/obesidad" (n=112), en la que los 5 primeros ingredientes botánicos consumidos habían sido identificados, y b) el total de muestra (N=2359), para aumentar la potencia de la prueba.

2.4.3 Resultados

Para elaborar este resumen se han seleccionado solo algunos de los resultados más relevantes. Del total de 2874 productos CAP consumidos, 252 (8,8%) fueron consumidos por "razones de peso corporal" (por 240 consumidores). Del total de 2359 consumidores de CAP, 112 (4,8%) estaban "a dieta de sobrepeso/obesidad". España es el país donde más encuestados respondieron consumir CAP "por razones de peso corporal" y estar "a dieta de sobrepeso/obesidad" (véanse Figuras 5 y 6). La alcachofa fue el ingrediente botánico más consumido a) por "razones de peso corporal", b) por "personas que hacen dieta de sobrepeso/obesidad" y c) por la tabulación cruzada de los dos grupos. Considerando los 5 ingredientes botánicos más utilizados por "razón de peso", se observó una proporción significativamente más alta de IMC>25 entre los consumidores de CAP que contenían alcachofa (*Cynara scolymus*) y té verde (*Camellia sinensis*), que en los consumidores que no tomaban estos dos ingredientes (en el caso de la alcachofa: 58,4% frente a 49,1% y en el caso del té verde: 63,2% frente a 49,7%); este resultado aparece al considerar toda la muestra (véase la Tabla 10). Considerando los 5 ingredientes botánicos más utilizados por personas que estaban “a dieta de sobrepeso/obesidad", se observó una proporción significativamente menor de IMC>25 entre los consumidores de productos que contenían piña (*Ananas comosus*), que en los no consumidores (38,5% frente a 81,5%); este resultado aparece cuando se utiliza la submuestra de personas que estaban “a dieta de sobrepeso/obesidad”. Sin embargo, cuando se utiliza toda la muestra, solo se observa una mayor proporción de IMC>25 entre los consumidores de CAP que contenían como ingrediente alcachofa (*Cynara scolymus*) respecto a los no consumidores (58,4% frente a 49,1% respectivamente) (véase la Tabla 11). Por otro lado, las tres primeras razones para tomar productos que contienen alcachofa (*Cynara scolymus*) fueron "peso corporal" (en 79 productos, de los cuales 47 fueron consumidos en España), "estómago/función digestiva" (79 productos, 37 consumidos en Alemania) y "colesterol" (32 productos, 21 consumidos en Alemania) (véase la Figura 7).

Figura 5. CAP consumidos por "razones de peso corporal" (%), por país

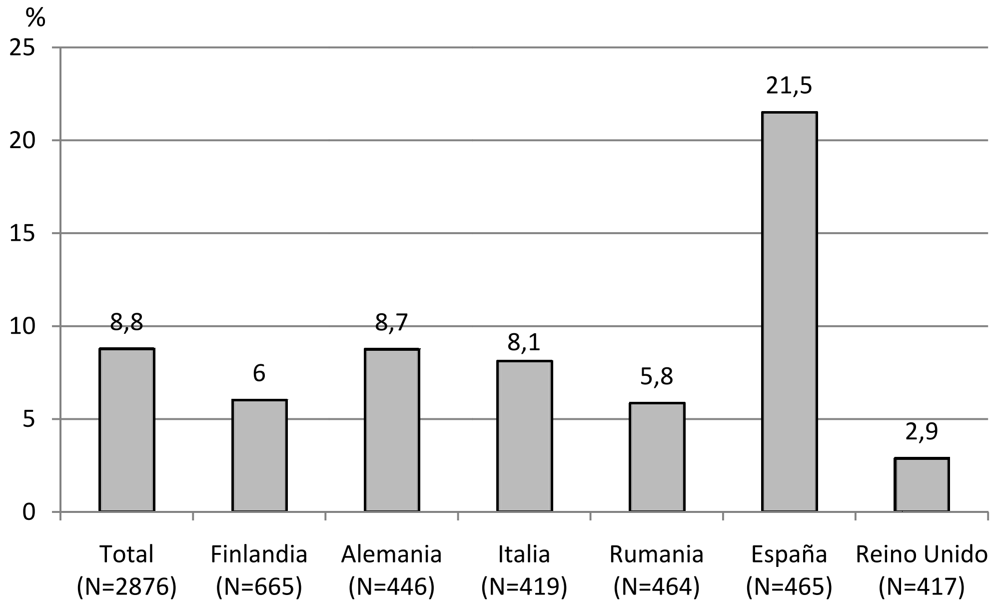


Figura 6. Consumidores de CAP que están "haciendo dieta contra el sobrepeso/obesidad "(%), por país

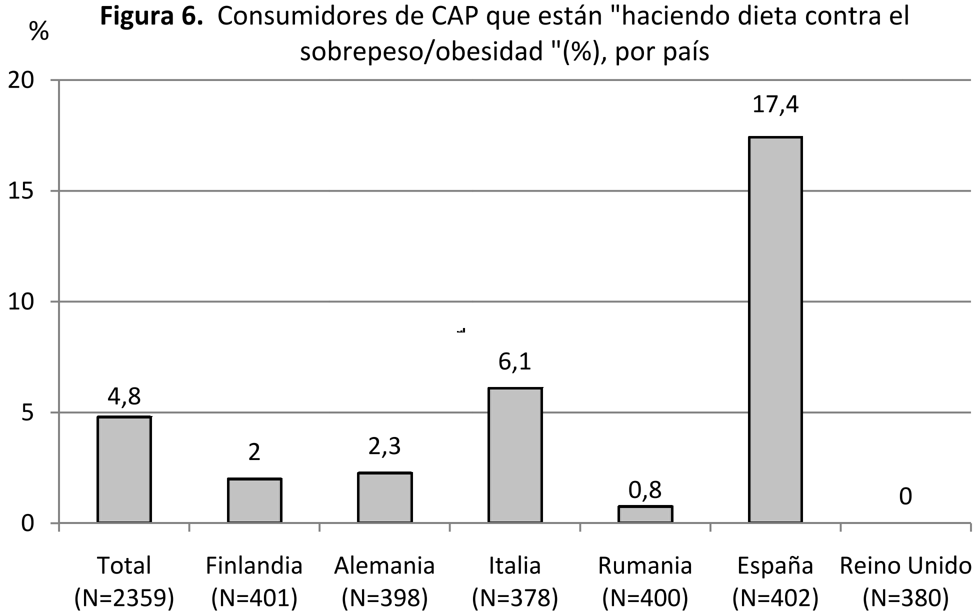


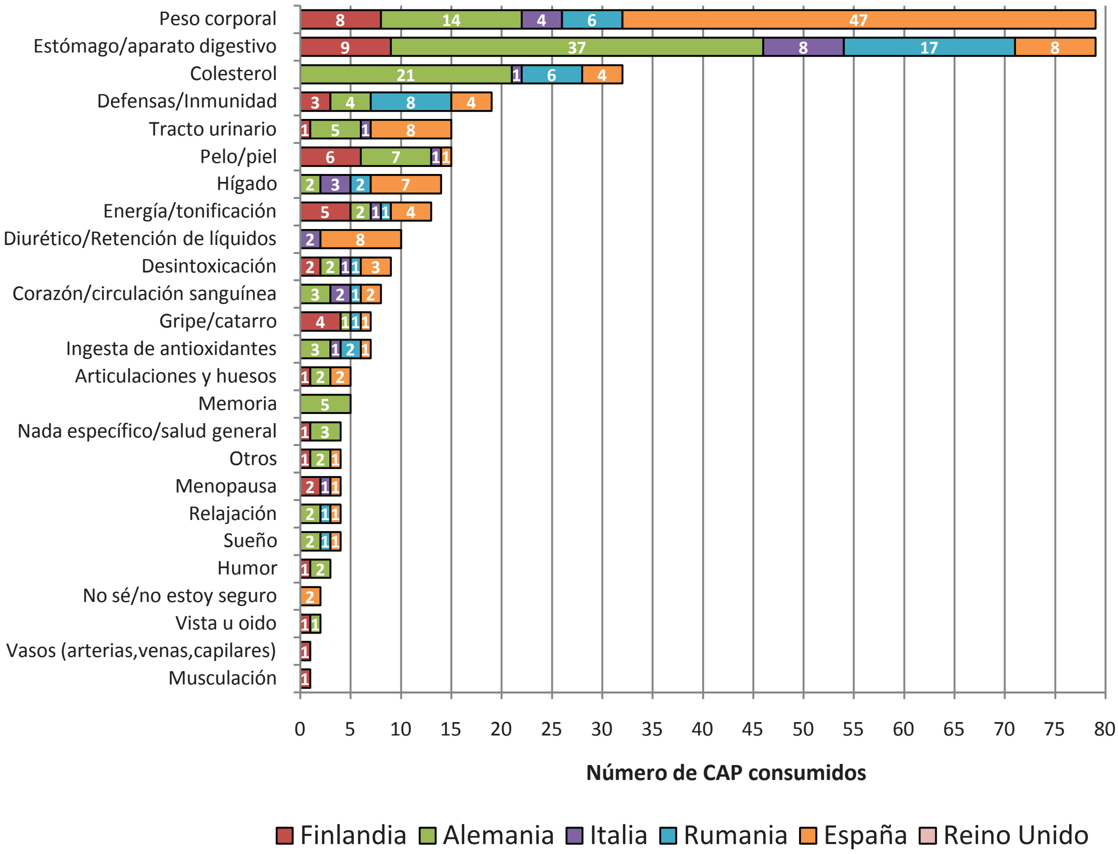
Table 10. Diferencias en la distribución del IMC entre consumidores y no consumidores de los 5 ingredientes botánicos más consumidos usados por quienes respondieron "razones de peso corporal" al usar CAP, cuando se utiliza a) la submuestra "razones de peso corporal" y b) la totalidad de la muestra de la encuesta.

		IMC				
		<25 kg/m²		**≥25 kg/m²**		
5 ingredientes botánicos más consumidos por "peso corporal"	**Grupo de consumo**	**n**	**%**	**n**	**%**	**χ^2 *Valor p***
a) Al utilizar sólo la submuestra de consumidores que respondieron "peso corporal" (N=240)						
Cynara scolymus (alcachofa)	Consumidores	24	33,3	48	66,7	0,168
	No consumidores	72	42,9	96	57,1	
Foeniculum vulgare ssp. (hinojo)	Consumidores	15	40,5	22	59,5	0,942
	No consumidores	81	39,9	122	60,1	
Camellia sinensis (te verde)	Consumidores	17	50	17	50	0,199
	No consumidores	79	38,3	127	61,7	
Vitis vinifera (vid)	Consumidores	6	26,1	17	73,9	0,152
	No consumidores	90	41,5	127	58,5	
Ananas comosus (piña)	Consumidores	10	47,6	11	52,4	0,456
	No consumidores	86	39,3	133	60,7	
b) Cuando se utiliza la totalidad de la muestra de consumidores (N=2359)						
Cynara scolymus (alcachofa)	Consumidores	72	41,6	101	58,4	**0,019**
	No consumidores	1113	50,9	1073	49,1	
Foeniculum vulgare ssp. (hinojo)	Consumidores	71	53,8	61	46,2	0,401
	No consumidores	1114	50	1113	50	
Camellia sinensis (te verde)	Consumidores	32	36,7	55	63,2	**0,043**
	No consumidores	1142	50,3	1130	49,7	
Vitis vinifera (vid)	Consumidores	43	49,4	44	50,6	0,878
	No consumidores	1142	50,3	1130	49,7	
Ananas comosus (piña)	Consumidores	21	60	14	40	0,244
	No consumidores	1164	50,1	1160	49,9	

Table 11. Diferencias en la distribución del IMC entre consumidores y no consumidores de los 5 ingredientes botánicos más consumidos por personas que están "a dieta de sobrepeso/obesidad", cuando se utiliza a) la submuestra de los que están "a dieta de sobrepeso/obesidad" y b) el total de la muestra de la encuesta.

		IMC				
		<25 kg/m²		**≥25 kg/m²**		χ^2
5 ingredientes botánicos más consumidos por personas "a dieta de sobrepeso/obesidad"	**Grupo de consumo**	**n**	**%**	**n**	**%**	***Valor-p***
a)Usando sólo la submuestra de consumidores que están "a dieta de sobrepeso/obesidad" (N=112)						
Cynara scolymus (alcachofa)	Consumidores	9	26,5	25	73,5	0,590
	No consumidores	17	21,8	61	78,2	
Foeniculum vulgare ssp. (hinojo)	Consumidores	5	29,4	12	70,6	0,511
	No consumidores	21	22,1	74	77,9	
Taraxacum officinale (diente de león)	Consumidores	3	21,4	11	78,6	0,866
	No consumidores	23	23,5	75	76,5	
Ananas comosus (piña)	Consumidores	8	61,5	5	38,5	**0,000**
	No consumidores	18	18,2	81	81,8	
Matricaria chamomilla (manzanilla)	Consumidores	1	9,1	10	90,9	0,243
	No consumidores	25	24,8	76	75,2	
b) Usando el total de la muestra de consumidores (N=2359)						
Cynara scolymus (alcachofa)	Consumidores	72	41,6	101	58,4	**0,019**
	No consumidores	1113	50,9	1073	49,1	
Foeniculum vulgare ssp. (hinojo)	Consumidores	71	53,8	61	46,2	0,401
	No consumidores	1114	50	1113	50	
Taraxacum officinale (diente de león)	Consumidores	39	48,8	41	51,3	0,787
	No consumidores	1146	50,3	1133	49,7	
Ananas comosus (piña)	Consumidores	21	60	14	40	0,244
	No consumidores	1164	50,1	1160	49,9	
Matricaria chamomilla (manzanilla)	Consumidores	32	47,8	35	52,2	0,681
	No consumidores	1153	50,3	1139	49,7	

Figura 7. Razones de salud para las que se usan CAP que contienen *Cynara scolymus* (alcachofa), por país.



III. CONCLUSIONES Y APORTACIONES ORIGINALES

Los resultados de la investigación desarrollada en esta tesis tienen importantes implicaciones para la salud pública. Desde hace años se sabe que el exceso de peso corporal general y central es un problema de salud pública creciente, que afecta a cada vez más sociedades, tanto las afluentes, como las que están en transición y las emergentes. También es conocido que este problema de salud pública está influenciado por muchos factores, y que los individuos afectados buscan todo tipo de estrategias de control/pérdida de peso. Algunos de estos factores y estrategias de control de peso se han analizado en esta tesis.

Por lo que respecta al capítulo 1, se han evaluado las tendencias de las tasas de prevalencia generales y centrales de sobrepeso y obesidad en la población adulta de Cataluña, España, en el período 1992-2003. También se ha estudiado la influencia de factores socio-económicos y socio-demográficos en estas tendencias. Las tendencias durante los diez años estudiados indican que los hombres catalanes cada vez pesaban más en general (IMC) y también alrededor de la cintura (PC), mientras que las mujeres catalanas tenían cinturas más anchas (PC). La prevalencia del IMC de obesidad masculina superó a la de las mujeres. El PC de obesidad siguió siendo más frecuente en las mujeres que en los hombres, especialmente en el caso de los grupos de población con niveles socio-económicos inferiores (niveles de ocupación y de educación más bajos). A pesar de las limitaciones del estudio, los resultados obtenidos se suman a las evidencias encontradas en otros artículos de que el fenómeno de la obesidad y el sobrepeso tiende a empeorar en Cataluña. Las conclusiones de la investigación deberían ayudar a orientar las políticas de salud pública y a diseñar campañas de prevención contra las tendencias crecientes de sobrepeso y obesidad. Estas intervenciones deberían poner especial atención en los hombres, en personas con un nivel socio-económico y de educación bajo, y en las poblaciones de menor tamaño. Por otra parte, los análisis también revelaron que el PC de obesidad continuó siendo más prevalente en las mujeres que en los hombres, especialmente las de los grupos socio-económicos inferiores (niveles de ocupación y educación bajos). La literatura ha demostrado que los cambios en el PC acompañan a cambios en los factores de riesgo cardiovascular; el PC también predice la morbilidad y la mortalidad y está fuertemente asociado con anomalías metabólicas. Por lo tanto, las conclusiones obtenidas en el capítulo 1 sobre las tendencias en la población femenina adulta catalana alentarían la toma urgente de medidas en relación al control de peso para mejorar la salud de este colectivo y prevenir las co-morbilidades de la adiposidad abdominal. En este sentido, debería ponerse especial atención en los grupos de menos recursos.

El estudio elaborado en este capítulo fue publicado en la revista *Public Health Nutrition* 2007 (factor de impacto (FI) en 2008: 2.123) (véase el Anexo IVa de esta tesis). Además, fue presentado en forma de póster en el Congreso de la SENC VIII, Valencia, 22-25 de octubre de 2008.

El capítulo 2 de la tesis ha examinado el posible uso del tabaco como estrategia de control de peso. De nuevo, la investigación se centra en la población de adultos catalanes de las dos encuestas ENCAT en el período 1992-2003. Se han evaluado las tendencias de prevalencia en los patrones observados de exceso ponderal general/de adiposidad central entre sujetos con diferentes hábitos tabáquicos. También ha examinado la asociación entre el tabaquismo y el exceso de peso general/central después de ajustar por posibles factores de confusión. Finalmente, la investigación muestra cómo estas relaciones cambian con las tendencias temporales (1992-2003) en la prevalencia de la obesidad y el tabaquismo. Aunque la causalidad no puede ser establecida, los resultados sugieren una asociación positiva entre fumar en exceso (>20 cigarrillos/día) y la adiposidad central en los hombres; el reducido número de mujeres que declararon ser fumadoras en exceso limitó la capacidad de examinar las asociaciones entre el tabaquismo excesivo y la obesidad central y la posibilidad de comparar los resultados en mujeres y hombres. Sin embargo, no se observó una asociación entre el ex-tabaquismo y el exceso ponderal general/de adiposidad central en la última encuesta.

En términos generales, estos hallazgos fortalecen los argumentos que promueven el abandono del tabaco para reducir la morbilidad y la mortalidad asociadas tanto con fumar como con la obesidad. Este capítulo contribuye a la evidencia global que ha analizado la relación entre obesidad y tabaquismo. Hasta ahora no se había estudiado esta relación para el caso de la población catalana. El manuscrito ha sido enviado a una revista científica (véase el Anexo IVb de esta tesis).

Finalmente, es importante destacar que uno de los aspectos más interesantes de los capítulos 1 y 2 es haber podido analizar las dos encuestas ENCAT, representativas, idénticas y separadas por diez años. Este hecho permite obtener una visión dinámica de cómo evoluciona la salud y los hábitos de la población catalana, y debería ayudar en la toma de decisiones en política de salud. Para esta tesis es el plus que permite poder hacer una buena contribución.

Los capítulos 3 y 4 exploran el consumo de CAP en seis países de la UE y la relación entre el consumo de CAP y el IMC auto-informado de sus consumidores. La motivación de esta investigación es que una amplia gama de CAP se utiliza popularmente para el control/pérdida del peso corporal. Los estudios presentados en estos capítulos se llevaron a cabo utilizando datos de la Encuesta PlantLIBRA de Consumidores de CAP 2011-2012 -del proyecto PlantLIBRA de la UE. Esta es la primera encuesta de consumidores de CAP realizada a nivel europeo.

El capítulo 3 presenta los resultados de la encuesta sobre el consumo de CAP. Se describen el tipo de producto consumido, la frecuencia de su consumo, y los ingredientes botánicos que se encuentran con mayor frecuencia en los productos consumidos. La obtención y manipulación de toda esta información es bastante compleja, y más teniendo en cuenta que el estudio considera 6 países de la UE. La encuesta es uno de los principales resultados del proyecto europeo PlantLIBRA y supone una contribución a la investigación en este sector a nivel europeo. Gracias a este proyecto y su encuesta, actualmente hay datos disponibles obtenidos directamente de los consumidores de seis países europeos que pueden ser utilizados en el futuro para realizar diversos tipos de investigaciones. Además, una nueva metodología ha sido propuesta y probada, que puede ser utilizada y mejorada por los futuros investigadores en este campo para generar más datos. Así por ejemplo, la incorporación de medidas de la ingesta de productos botánicos en las encuestas dietéticas nacionales proporcionaría datos muy necesarios para la evaluación exhaustiva de los riesgos y beneficios de estos productos a nivel europeo, y para la formulación de políticas por parte de la CE y las autoridades nacionales. Los primeros resultados de la encuesta se difundieron a través de numerosas presentaciones antes del fin del proyecto y mediante una publicación en la revista *PLoS One* 2014 (FI en 2013/2014: 3.53) (véase el Anexo IVc de esta tesis).

Por último, los datos de la Encuesta PlantLIBRA de Consumidores de CAP permitieron analizar la posible relación entre el consumo de CAP y el "exceso de peso corporal". El capítulo 4 proporciona una visión general de los ingredientes botánicos de los CAP consumidos por "razones de peso corporal" y por personas que están "a dieta de sobrepeso/obesidad"; también explora la relación entre el consumo de estos ingredientes botánicos y el IMC auto-informado de sus consumidores. Aunque nuestro análisis está limitado por el pequeño tamaño de la muestra y por la falta de "datos de composición" (cantidades reales de los ingredientes botánicos ingeridos), este estudio representa un primer intento (y espero que no el último) en la exploración de la relación entre el consumo de CAP y la obesidad. En este sentido, este estudio ha mostrado que en algunos países europeos como España el consumo de CAP específicos para el control/pérdida del peso corporal es bastante prevalente. Los resultados obtenidos deberían alentar a la comunidad investigadora a profundizar en el análisis del consumo de estos productos. Los estudios futuros deben en lo posible ser a largo plazo, con muestras de gran tamaño de la población general (es decir, consumidores de CAP y no consumidores, idealmente como parte de las encuestas regionales/nacionales de salud/nutrición/terapias alternativas y complementarias de uso de la salud), y que permitieran recoger los datos incluidos en la etiqueta de los productos, como los ingredientes, cantidades y dosis. Esta información adicional ayudaría a entender muchos aspectos relacionados con la comercialización, el consumo y la eficacia de los CAP. Es importante seguir recopilando datos sobre los productos botánicos utilizados por una parte de la población en la pérdida de peso, para entender por qué y cómo se consumen estos productos y determinar sus efectos en la salud (IMC, PC, y muchos otros indicadores).

La investigación de este capítulo fue presentada en forma de póster en el III Congreso Mundial de Nutrición y Salud Pública, Las Palmas de Gran Canaria, 9-12 de noviembre de 2014 (véase el Anexo IVd de esta tesis). El artículo está pendiente de envío a una de las siguientes revistas (FI en 2013-2014): 1) *Phytomedicine* (2.877) o 2) *Plant Foods For Human Nutrition* (2.416) o 3) *Phytotherapy Research* (2.397) o 4) *Planta Medica* (2.339).