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Energy Balance, a new paradigm and methodological issues: the ANIBES study in Spain

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Abstract

***Energy Balance* (EB) is an important topic to understand how an imbalance in its main determinants (energy intake and consumption) may lead to inappropriate weight gain, considered to be "dynamic"and not "static". There are no studies to evaluate EB in Spain and new technologies reveal as key tools to solve the common problems to precisely quantify energy consumption and expenditure at population level. Within this context, the increasing complexity of the diet, but also the common problems of under and over reporting in nutrition surveys have to be taken into account.**

The overall purpose of the ANIBES ("Anthropometry, Intake and Energy Balance in Spain") Study was to carry out an accurate updating of foods and beverages intake, dietary habits/ behaviour and anthropometric data of the Spanish population as well as the energy expenditure and physical activity patterns, by the use of new tested instruments (i.e. tablet device to assess energy intake and accelerometer to evaluate physical activity). This new ANIBES Study will contribute to a better knowledge of the different key factors contributing to EB in Spain.

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BALANCE ENERGÉTICO, UN NUEVO PARADIGMA Y ASPECTOS METODOLÓGICOS: ESTUDIO ANIBES EN ESPAÑA

Resumen

El *balance energético* (BE) o equilibrio energético se refiere "simplemente" a que debemos ingerir la misma cantidad de energía que gastamos. Conocer el concepto de BE y aplicarlo a nuestras vidas es quizá el factor más importante para mantener una buena salud y tratar de prevenir la obesidad. Sin embargo, la teoría no es sencilla llevarla a la práctica ya que, por un lado, en este ya avanzado siglo XXI desconocemos todavía en gran medida lo que comemos, en definitiva, nuestra alimentación. Y ésta es cada vez más compleja, lo que dificulta sin duda controlar adecuadamente este lado de la "balanza", la ingesta. Pero además, en el otro lado, el correspondiente al gasto energético, aún es peor conocido y hay muy escasa información en la cuantificación adecuada del mismo. Debe recordarse, además, que no debemos estudiar aisladamente los componentes del BE, sino de manera integrada, y como interaccionan. Problemas como la infravaloración de la ingesta de energía, y la sobrevaloración del gasto, son frecuentes en la mayoría de las encuestas nutricionales, impactando más en aquellos grupos de población en los que el control del BE resulta aún más necesario. El empleo de las nuevas tecnologías abre numerosas posibilidades para las encuestas de balance energético. Precisamente, la innovadora metodología (empleo de "tablet" para cuantificación de la ingesta, y de acelerómetros para el nivel de actividad física) en el reciente Estudio ANIBES ("*Antropometría, Ingesta, y Balance Energético en España*"), representativo de la población española, y que hemos desarrollado, proporciona una herramienta útil y actualizada para un mejor conocimiento del *balance energético* de la población española, como se pone de manifiesto en el presente artículo.

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Introduction and goals

Energy Balance (EB) is defined as the state achieved when energy intake equals energy expenditure and is considered to be "dynamic" and not "static"[1]. The concept of energy balance for regulating body weight is simple in principle. When energy expenditure exceeds energy intake, weight is lost. When energy intake exceeds energy expenditure, weight is gained[2]. Human physiology complies with the first law of thermodynamics, which states that energy can be transformed from one form to another but cannot be created or destroyed. A fundamental principle of nutrition and metabolism is that body weight change is associated with an imbalance between the energy content of food eaten and energy expended by the body to maintain life and to perform the variety of physical work. Such an EB framework is a potentially powerful tool for investigating the regulation of body weight[3].

Energy intake (EI) includes three major macronutrient groups—carbohydrates, proteins, and fats—and alcohol. Once ingested, the net absorption of the major macronutrient groups is variable and incomplete,with fecal losses accounting for 2–10% of gross intake [3,4]. The net absorption of dietary energy components varies among individuals and is dependent on the specific foods eaten, how they are prepared, and intestinal factors. The metabolizable energy of a diet represents the difference between the absolute energy of ingested substrates and the energy losses found in feces and urine. Commonly used energy densities for carbohydrate (4 kcal/g, 17 kJ/g), protein (4 kcal/g, 17 kJ/g), and fat (9 kcal/g, 38 kJ/g) represent population averages for metabolizable energy available to cells for conducting the different biological processes[4].

Digestibility depends on the composition of the food item and on its content of fiber and other indigestible components. Such components can mechanically limit the access of digestive enzymes to food that would potentially be digestible. These effects can have a large impact on the absorption of ingested macronutrients. The variability in absorptive efficiency depends on any additional factors (eg, gut flora, food preparation, diet composition), which may explain the individual differences in metabolizable energy. Other factors to influence EI are: the increasing complexity of the food market nowdays (i.e. over 30,000 available products for shopping); total intake; energy density; timing and composition of diet relative to physical activity; food liking and disliking; social and economical context; or current body weight and composition [3,4]. Absorbed carbohydrates, proteins, and fats are transformed in vivo to substrates that can ultimately either be oxidized to produce metabolically useful energy that drives biological processes or they may be stored [5].

Humans expend energy through resting metabolic rate (RMR), which is the amount of energy necessary to fuel the body at rest; the thermic effect of food (TEF), which is the energy cost of absorbing and metabolizing food consumed; and the energy expended through physical activity [2,6]. RMR is proportional to body mass, particularly the amount of fat-free mass. There is also, however, a large variability in RMR (250 kcal/d ;1000 kJ/d) that is not explained by differences in body composition[7].The TEF is proportional to the total food consumed and, in a typical mixed diet, makes up 8% to 10% of total energy ingested. Diet composition has a strong effect on TEF, and a hierarchy of macronutrient effects on the magnitude of TEF, the highest for protein and lowest for fat. Normally, TEF is assumed to be a fixed percentage of EI, but variation between and within individuals also occurs [7,8]. The energy for physical activity, the most variable component of energy expenditure, consists of the amount of physical activity performed multiplied by the energy cost of that activity and can be further partitioned into exercise energy expenditure and non exercise activity thermogenesis [9,10].

In summary, the key factors that may regulate the energy expenditure *side* of the balance are: resting metabolic rate; activities of daily living/level of sedentary behavior; metabolic cost of digestión, absorption and metabolism; amount (min/d); type, timing and intensity of physical activity; thermogenesis; and current body weight and composition.

The different components of the energy balance equation continuously change over time[11]. Beginning at conception, and remains positive, on average, throughout growth and development[12]. This positive energy imbalance is reflected by increasing body weight. If adult weight is then maintained over the long term, average EB approaches zero, and an approximate average state of energy balance should be present. However, most adults gain fat throughout their lives and in later life lose skeletal muscle; although the energy content of body fat change is much higher than that of lean tissue change. Thus, even with weight stability, "perfect" energy balance over the long term does not occur in most older adults [2,13,14].

In terms of a short term period, over a 24-h period, a typical person eats several meals during the day, and EB is strongly positive during and after each meal. Energy output is continuous but with increases due to episodic physical activity and reduction during sleep. In consequence, EB is thus highly variable even over just a 1-d period. In addition, most adults also vary their daily eating and activity patterns; thus, EB should be seen as a dynamic rather that a static state since it also varies from day to day, and EB may be achieved only when averaged over longer time periods. The energy content of a given meal is highly variable between individuals and highly variable between meals in an individual. However, the variation in total caloric intake summed across all meals over a day is far less variable. This suggests that there is meal-to-meal compensation of intake[13]. In addition to variation in intake between meals on a given day, we also vary the amount of food eaten each day. On the contrary, energy expenditure rarely shows the same degree of variation across days. Hence, and importantly, we are almost perpetually in energy imbalance on the time scale of hours or days, and even through the whole life cycle.

Furthermore, we know that the components of energy balance can be influenced by changes in each other as a consequence of positive or negative EB, which act to defend body energy stores, to maintain energy balance, and to prevent shifts in body mass[2]. We know that if energy balance were not controlled by such a system and were subject *only* to behavioral mechanisms controlling food intake and energy expenditure, most people would routinely experience wide swings in body weight over short periods of time. Therefore, the relative stability of body weight from day to day is consistent with the view that EB is subject to physiological control.

The energy balance literature and information about how our modern lifestyle differs from decades ago, hypothesize that human physiology developed under circumstances that conferred an advantage for achieving energy balance at a relatively high level of energy expenditure or high energy flux, which was first shown by Mayer in the 1950´ by their observation that energy intake was better matched to energy expenditure when people were physically active[15]. It is well known that over the past century and continue, the physical activity level of most of the population has declined substantially. Although it is theoretically possible to avoid weight gain in this situation, the fact that few people have accomplished this suggests that it is difficult to maintain EB at a low energy throughput [16,17].

Food restriction is a common strategy for reducing excess body weight and/or treating obesity[18]. However, food restriction produces weight loss, but it also produces compensatory decreases in other components of energy balance, such as decreases in energy expenditure and body energy stores, and even an increase in hunger[4]. Because energy requirements fall with weight loss, a dangerous and unhealthy strategy for weight loss maintenance is trying to match a lower level of energy expenditure with a lower energy intake. It has to been remained that lowering energy intake is opposed by biology and the environment. An additional problem could be that at a reduced energy intake level, nutrients (mainly vitamins and minerals) dietary reference intakes may not be achieved, which may represent a key problem in some vulnerable groups (e.g. children and elderly). Finally, at high energy expenditure, it would be easier to comply with the principle that an adequate nutrition it is health but also pleasure. In consequence, it matters how EB is achieved, at high or low level[1].

It is therefore important to recognize that the EB system is interactive and complex: a change in one component can affect one or more other components. Recently, a Panel of Experts identified the following important gaps in our knowledge, and asked for future investigation[13]:

1. Although we know much from short-term studies about the major components of energy balance, our knowledge is still deficient regarding their interaction over the long term. Therefore, long-term, longitudinal studies to learn the details of the relations between components of energy balance and changes in body composition and weight among children and adults are needed.

2. It has been shown that biological and psychological factors affect the components of energy balance. But generally, these have been studied independently of one another and an integrative approach is required. We need to know the relative importance of preingestive factors on energy intake, energy balance, and the physiologic response to a meal.

3. Although our knowledge of the broader implications of physical activity and exercise have been investigated, we need to understand the effects of different doses (volume, intensity, pattern, timing) and types (endurance, resistance) of exercise on: a) total daily energy expenditure and its components, b) EI and food preferences, and c) body composition and body weight in children and adults.

4. The individual variation in weight-loss response to energy balance interventions is striking, and therefore we need to know the mechanism or mechanisms responsible for the underlying active compensatory differences in energy intake, food preferences, and body weight in children and adults. In particular, we have almost no information from energy balance studies subsequent to weight loss during the difficult period of weight maintenance.

5. And very important, measurements of energy input and output are neither precise nor accurate enough to allow the calculation of energy balance over the appropriate timeframe needed to understand the mechanisms responsible for excess weight gain. Accordingly, we need to develop new methods that can reliably measure energy balance over extended time periods in free-living people.

The EB is not well defined for the Spanish population and it is essential to approach it with the aim of being able to properly establish the energy requirements for our population and the subsequent Reference Intakes. It seems essential to improve the tools for studying the energy intakes and losses of "free living" independent subjects[13]. In this regard, the tools such as databases of the composition of quality foods, especially regarding energy and serving sizes, should be improved, as clearly stated at the recent (2013) Consensus Document and Conclusions on "Obesity and Sedentarism in the 21st Century: What can be done and what must be done?"[19].

Different valuable dietary surveys have been conducted in Spain, although to the best of our knowledge, no one has attempted to specifically approach EB. Briefly, the first Food Consumption Survey was performed in 1956 under the National Health Survey. Further, several Spanish Food Consumption and Nutrition

Surveys have been carried out (ENNAs; 1964-1965, 1980-1981 y 1990-1991) mainly in collaboration with the National Statistics Office (INE, Spain)[20-23]. From 1987 onwards, the current Ministry of Agriculture, Food and Environment (MAGRAMA) in Spain launches the National Food Consumption Survey (Panel), in for which the Spanish Nutrition Foundation (FEN) is responsible for analyzing the dietary patterns and energy/nutrients intake of the Spanish population since the year 2000 onwards[24]. At national level, the current AECOSAN (Spanish Agency for Consumer Affairs, Food Safety and Nutrition) recently carried out the ENIDE Survey (Encuesta Nacional de Ingesta Dietética) (AECOSAN, 2012)[25]. At present, the so-called ENALIA (Encuesta Nacional de Alimentación en la población Infantil y Adolescente) Survey in children and adolescents from Spain is being carried out also under the auspices of AECOSAN. The latter updates the reference survey in Spain in children and young people (2-24 years old) called EnKid[26], and the AVENA study, a multicenter nutrition survey in Spanish adolescents[27]. However, when approaching the other main EB determinant ("energy expenditure") studies are much less frequent even scarcer and lack of accuracy. The most recent National Health Survey in Spain (2013)[28] revealed that four out of ten persons (41.3%) of the adult Spanish population is considered as sedentary, higher for women (46.6%) than for men (35.9%) (they do not perform any kind of physical activity during their leisure time). Considering both their main and their leisure time activity, 40.9% of the adults (49.4% males, 32.4% females, aged 15-69 years) perform strenuous to moderate weekly physical activity. There is consensus at present that not only physical activity level but also inactivity and/or sedentary behavior should be taken into account and quantified [3,6].

The ANIBES ("Anthropometry, Intake, and Energy Balance in Spain") Study, aims at adding new scientific-based evidence to describe the interplay among energy intake, energy expenditure, and body energy stores and how an understanding of energy EB must be considered as an useful tool either at individual or population level.

Anibes study design and sampling procedure

The design of the ANIBES Study aimed a sample size which should be representative of all individuals living in Spain (excluding the autonomous cities of Melilla and Ceuta) aged 9-75 years, living in municipalities >2,000 inhabitants. The universe considered about 37 millions of inhabitants. The initial potential sample was 2,634 individuals, and the final sample was 2,009 individuals (2.23% error and 95.5% confidence interval). In addition, for the youngest groups (9-12, 13-17 and 18-24 years old), a boost was considered in order to have at least a n=200 per age group (error +/-6.9%) to increase the statistical power. Therefore, the random sample plus booster was 2,285 participants (Table 1).

Table I
Distribution of the sample for the ANIBES study.

		SAMPLE (n)		
		Initial targeted sample	*Final sample*	*Final + Boost*
	Base	*2634*	*2009*	*2285*
SEX	Men	1309	1013	1160
	Women	1325	996	1125
AGE (yr)	Infants 9 – 12	240	100	213
	Adolescents 13 – 17	246	124	211
	Adults 18 – 64	1911	1588	1655
	Elderly 65 – 75	237	197	206

In the ANIBES sample, 50.4% of adults (aged 9-75 years) were men and 49.6% were women. The sample reflects the distribution of males and females in the general population within Spain. A more detailed description of the sample for the ANIBES study is shown in Table 1.

The sample quotas according to the following variables were:

- Age groups (in years): 9-12, 13-17, 18-64 and 65-75.
- Gender: men and women.
- Region: 7 Nielsen areas (Northeast, Levant, South, West, North Central, Barcelona, Madrid) and Canary Islands.
- Habitats size: 2,000 to 30,000 inhabitants (rural population); from 30,000 to 200,000 inhabitants (semi-urban population) and over 200,000 inhabitants (city/town population).
- Additionally other factors for sample adjustment were considered: rate of unemployment; % of foreigners (immigrant population), level of physical activity, or, education and economical level.

Study was conducted through a stratified multistage sampling and for more coverage and representativeness, 128 sampling points were used, with 90 interviewers allocated in 11 areas and 12 coordinators, all previously trained by the *Spanish Nutrition Foundation* (FEN) (Figure 1). No previous pre-recruitment was considered, which minimized the risk of bias in responses.

The final protocol was approved by the Ethical Committee for Clinical Research of the Region of Ma-

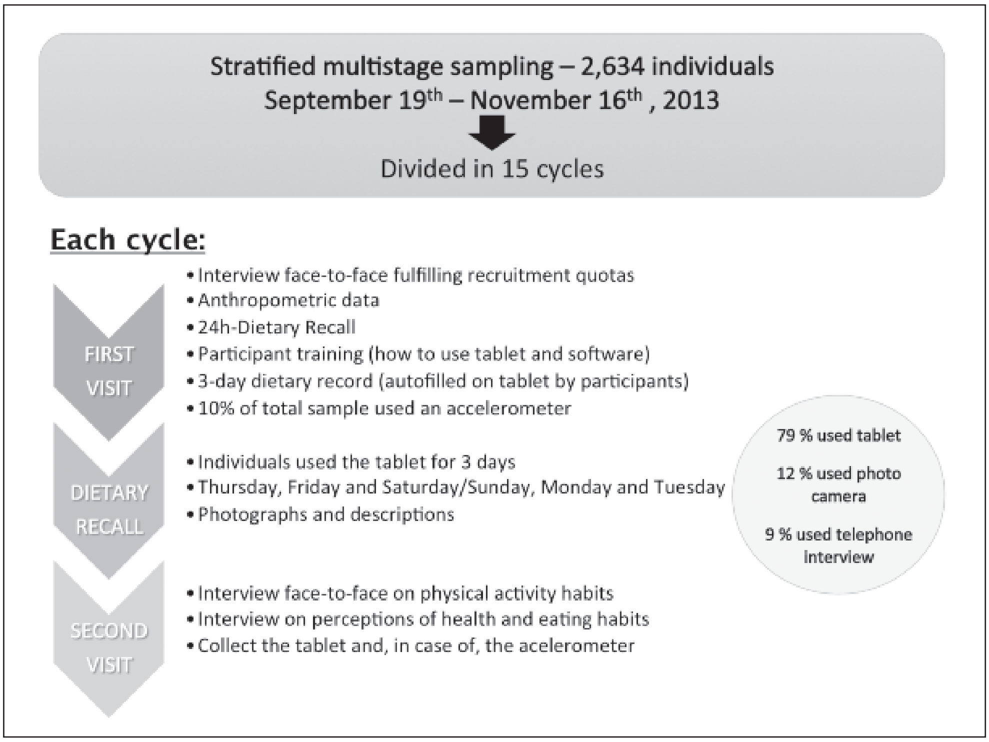

Fig. 1.—General scheme of the ANIBES Study in Spain.

drid (Spain). The final fieldwork was carried out from mid-September to November (three months), 2013.

Two **pilot studies** were previously carried out, as follows:

Once the methodology was developed, a first pilot study was carried out in June 2013. For this purpose, 2,060 individuals were contacted: 162 (7.8%) agreed to have the first visit/interview, 142 participated at the second visit/interview, but only 97 were able to make the three-days dietary record by using the tablet. Finally, only 57 participants were considered as fully eligible. Therefore, a high rate of non-responders was observed mainly in the older age groups and parents of children and adolescents. The first pilot study allowed reviewing several issues, both software and questionnaires.

Once the results from the pilot study were completed, several *working/discussion groups* were created in order to improve the study design, protocols, software and manuals. Therefore, four groups (one of interviewers; two mixed groups of young adult people from 25-35 years old; one group of parents with children aged 9-17 years) worked in order to improve the deficiencies observed during the fieldwork.

A second pilot study was carried out in order to evaluate the improvements after the first pilot study and comments and recommendations from the working groups. A total of 60 individuals (52 used tablet device; 5 photo camera; 3 by phone interview) participated. The second pilot study demonstrated the efficacy of the amendments made and validated the tools and questionnaires to be used later during the main fieldwork of the ANIBES Study.

Final Fieldwork

According to the number of interviews to be potentially targeted at the sampling point, one or more random initial routes for the sampling process were considered. The later criteria were not used for municipalities over 100,000 inhabitants where a postcode proportional criterion was considered. In the initial route, the apartment building or family housing was randomly selected, as well as the first household to be approached. Non-eligible addresses include vacant or derelict properties and institutions. If the *uptake* was positive, limits to be considered for a potential participant were:

Apartment building:

- 1-10 units, only one potential participant.
- 11-20 units, two potential participants as maximum.
- 21-50 units, three potential participants maximum.
- >50 units, four participants.

For family housing, one possible participant per 10 units was the rule used.

The survey was designed in order that no more than one adult and one child were selected from a household. This meant that adults living in households with one or more adults, and children in households with one or more children were less likely to be selected than were adults or children in single adult/child households.

All interviewers, call centre and dieticians-nutritionists working on the ANIBES study were briefed and trained before undertaking an assignment and were monitored during their assignment. All interviewers attended a two-day training course designed by the FEN where they were fully briefed on the protocols and administration of the survey. Fieldworkers were also issued with comprehensive written instructions covering survey procedures and measurement protocols. The briefing sessions covered background and content, doorstep approach, questionnaire administration (including practice sessions), placement and collection of self-completions and ActiGraphs and the placement, checking and collection of the three-day food tablet diaries and 24h-dietary recall and training in anthropometric data collection. After the briefing, "early work" checks were carried out at the two pilot studies that were carried out.

In order to cover a broad range of dates and to optimize the devices to be used during the study, several stages were designed (Figure 1), and comprised of:

Stage 1: the interviewer visits

A letter and leaflet describing the purpose of the survey were previously posted in potential targeted apartment building/family housing at the sampling points. A few days later, interviewers visited the addresses to determine whether the address was private, residential and occupied. They then carried out the selection process as already explained.

Interviewers carried out two main visits to households who agreed to participate:

The **first visit** ("face-to-face") with an approximate duration of 60 minutes comprised the following items:

a) **Identification of the trained interviewer,** as a collaborator of the FEN. The interviewer explained the main goals of the study, the design and stages, the novelty of the tools to be used for collecting food intake and recording physical activity, as well as offered to have a feedback report at the end of the study that included main results, dietary and physical activity advice, etc. The potential participant also received a letter from the principal investigator of ANIBES Study, and was informed for participation in the study. At this point, the potential participant was asked to sign the letter of consent for participation in the study.

b) **Inclusion/exclusion questionnaire**: the interviewer verified through a filter questionnaire that the participant was eligible for the ANIBES Study after reviewing the inclusion/exclusion criteria.

Several exclusion criteria were applied:

Those individuals living in an institution (e.g. colleges; nursing homes, hospitals, etc.)

Individuals following a therapeutic diet due to a recent surgery or any medical prescription.

If they were suffering a transitory pathology (i.e. flu, gastroenteritis, chicken pox, etc.) at the time of the fieldwork.

Individuals employed in areas related to consumer science, marketing or the media.

However, individuals under the following conditions were considered eligible to be included:

Those following dietary advice such as for prevention of hypertension, diabetes, hypercholesterolemia or hyperuricemia.

Pregnant and lactating women.

With diagnosed allergy and/or food intolerance.

Suffering a metabolic disease such as hyperthyroidism or hypothyroidism.

c) **Anthropometric measurements:** the trained interviewer collected the different measures following the procedures tested before at the two pilot studies:

Height: by triplicate using a *Stadiometer model Seca 206 (Medizinische Messsysteme und Waagen seit 1840, Hamburg, Germany)*.

Weight: one determination in a weighing scale model *Seca 804* (*Medizinische Messsysteme und Waagen seit 1840, Hamburg, Germany)*. This scale provide information about BMI, percentage of body fat and percentage of body water.

Waist circumference: by triplicate using a tape measure model *Seca 201*.

d) **24-h Dietary Recall**: an *adhoc* questionnaire was designed and previously checked and modified at the pilot studies. During the interview the participant recalled the food intake for the past 24 hours (working days). Food quantities were assessed by using of household measures, food models, pictures, or the brands. No prior notification was given to the subjects about whether or when they would be interviewed about their food intake. Information on food consumption was recalled per day, per meal and in between meals. The 24-h dietary recall was designed to further verification of the information collected at the Tablet, but also to make the participant more familiar with the type of information to be recorded in the diet record during the three-days period.

e) **Tablet device for collection of dietary data: the three-day food diary**:

All the participants were provided with a tablet device (*Samsung Galaxy Tab27.0.*) and instructed on how to record by taking pictures of all foods and drinks consumed during these three days, both at home and outside. Pictures had to be taken before and after finishing. Additionally, a brief description of the meals, recipes, brands, etc. had to be also recorded with the device. A specific software ("IPSOS Mobile for ANIBES") was designed which allowed to save the uncompleted information before sending it for codification. The tablet was designed only to be used to collect information related to ANIBES Study and no other uses were allowed.

A toll-free telephone number attended by call center operators of ipsos, trained by dieticians-nutritionists, was also available for the participants in order to answer any questions about the software, device working, food and beverage record, etc. Interviewers carried out a food diary check visit with participants on the second visit or third day of recording, either in person or over the telephone, with the aim of collecting missing details for foods recorded after initial codification process was completed and lack of information was detected. A manual of procedures to facilitate food collection was also given to the participants. Participants were also informed that an insurance would cover any accident or incidence with the devices, although they were asked for correct and watchful functioning and maintenance.

The different days of the week would (as far as possible) be equally represented as each cycle always included two working days (Monday and Tuesday or Thursday and Friday) and one weekend day (Saturday for Thursday and Friday cycle or Sunday for Monday and Tuesday cycle).

f) As an alternative to the tablet device, if the participant declared or demonstrated that he/she was unable to use it, other possibilities were offered: **photo camera and paper** or **telephone interview**. In both cases, the information to be collected was the same as with the tablet.

g) At the end of the first visit, the date for the second interviewer visit was agreed, as well as the telephone calls to be made for check up at the end of the collection of the data, if necessary.

h) **Accelerometer device to quantify physical activity level:** The objective physical activity measurements were obtained with an accelerometer ActiGraph (model GT3x y GT3x+; *ActiGraph, Pensacola, FL, USA*). This provides a measure of the frequency, intensity, and duration of physical activity and allows classification of activity levels as sedentary, light, moderate and vigorous. Individuals were asked to wear the ActiGraph on a belt above the right hip, during three consecutive full days including its cycle of the three days food & beverages dairy record by the tablet. Objective measurements of physical activity were taken using the ActiGraph, which recorded vertical movement, where the number of movements ('counts') increased with the intensity of activity. For any individual, the accelerometer recorded different periods during the day spent at different levels of activity, i.e. differing levels of 'counts per minute' (cpm), while they were being sedentary or engaging in light, moderate, or vigorous activity. This provided a measure of the frequency, intensity, and duration of physical activity and allowed classification of activity levels as sedentary, light, moderate and vigorous. Individuals were asked to wear the accelerometer on a belt above the right hip, during waking hours for three consecutive full days in parallel with the three days of food & beverages dairy record by the tablet. For the present study, the minimum wear time criterion for inclusion in analysis was set at three days. The average daily cpm for each participant was calculated as a weighted average based on the probability of wear/non-wear (for a minimum wearing time of at least eight hours per day). The participants were also provided with a sheet to be filled in with the periods (hours/minutes) of non-wear (shower, swimming, etc.). For those participants that agreed to wear the accelerometer (n=206) to quantify the physical activity, the device was activated coincident with the Tablet based three-day food diary**.** The subsample was selected following the same criteria for representativeness as for the total sample included in the study. After collecting the accelerometer devices at the second interviewer visit, they were sent to IPSOS in order to download the recorded information from the participant (physical activity, but also additional data such as sex, date of birth, height, and weight) and to recharge the battery for the next participant. The recorded information by the accelerometer in the subsample (167 adults and 39 children) was further used to validate the physical activity questionnaire administered to the whole sample, and to build a mathematical model to quantify energy expenditure in combination with different standard formulas.

The **second visit** ("face-to-face") with an approximate duration of 60 minutes comprised the following items: detailed interview about physical activity (IPAQ questionnaire for children and adolescents modified according to the HELENA study[29]), and a detailed interview by using validated questionnaires previously tested at the pilot studies, designed to gain insights from the participants on important food safety, nutrition and health-related topics, was also scheduled. In addition, the tablet device and the accelerometer were collected. Participants who were considered "fully productive" according to the completion of the stages, were asked whether they would like to receive feedback on the analysis of their diary and how was this compared to nutrient intake recommendations. The feedback also included general information related to healthy eating advice.

- A summary of the ANIBES fieldwork follows:
- Fieldwork dates: September 19th through November 16th, 2013, structured in 15 different cycles/stages.
- 90 interviewers and 12 coordinators.
- Equipments:
  - 426 *tablets devices*
  - 90 devices for anthropometric measurements (weighing scale, stadiometers, tape measure).
  - 87 accelerometers.
- Devices employed
  - 79% of the sample used *Tablet*
  - 12% used photo camera
  - 9% used telephone interview

A more detailed distribution of the devices used by sex and age group is shown in Table 2.

Table II
Devices used according to sex and age groups for the ANIBES study.

		SAMPLE (n)											
		Initial targeted sample				*Final Sample*				*Final sample + Boost*			
		DEVICE				*DEVICE*				*DEVICE*			
		Base	*TABLET*	*PHOTO CAMERA*	*TELEPHONE*	*Base*	*TABLET*	*CAMARA*	*TELEFHONE*	*Base*	*TABLET*	*CAMARA*	*TELEPHONE*
SEX	Base	2634	2077	320	237	2009	1568	253	188	2285	1804	279	202
		100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
	Men	1309	1038	156	115	1013	800	124	89	1160	922	143	95
		50%	50%	49%	49%	50%	51%	49%	47%	51%	51%	51%	47%
	Women	1325	1039	164	122	996	768	129	99	1125	882	136	107
		50%	50%	51%	51%	50%	49%	51%	53%	49%	49%	49%	53%
AGE (yr)	Base	2634	2077	320	237	2009	1568	253	188	2285	1804	279	202
		100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
	Children 9 – 12	240	201	29	10	100	82	15	3	213	178	27	8
		9%	10%	9%	4%	5%	5%	6%	2%	9%	10%	10%	4%
	Adolescents 13 – 17	246	221	21	4	124	113	8	3	211	190	18	3
		9%	11%	7%	2%	6%	7%	3%	2%	9%	11%	6%	1%
	Adults 18 – 64	1911	1571	207	133	1588	1300	176	112	1655	1361	180	114
		73%	76%	65%	56%	79%	83%	70%	60%	72%	75%	65%	56%
	Elderly 65 – 75	237	84	63	90	197	73	54	70	206	75	54	77
		9%	4%	20%	38%	10%	5%	21%	37%	9%	4%	19%	38%

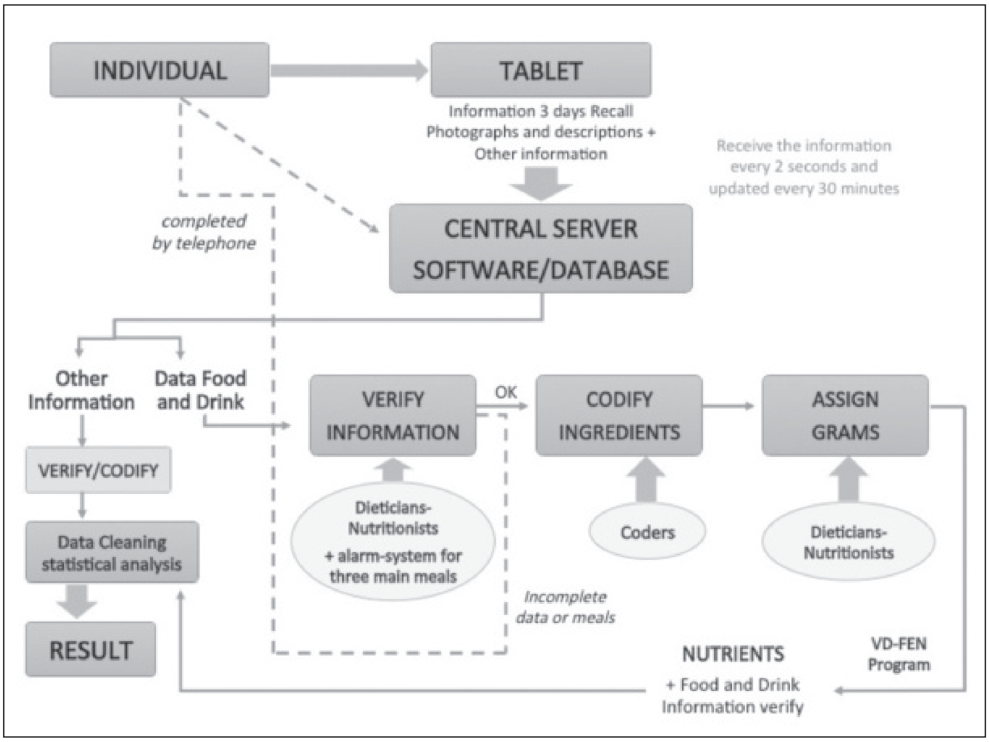

Fig. 2.—General scheme of the protocol followed for data collection, processing, cleaning, and codification during the ANIBES Study in Spain.

Data processing

Figure 2 shows an scheme for a better understanding of the data processing, quality control,cleaning of the data, and codification and verification stages.

The innovative technology used in this study allowed that all the collected information could be verified and codified in nearly *real time*. For that purpose, participants were asked to record everything eaten or drunk over three consecutive days. As already explained, when placing the *tablet* device, interviewers followed a protocol to explain the method, taking participants through the different sections including the instruction page, how to describe details of food and drink and portion sizes and several examples. In addition to the detailed information about what and how much was eaten, participants recorded for each eating occasion: where they were, who they were eating with and what they were doing (for instance, of they were watching TV or not). After each day, participants recorded if their intake was typical for that day (and if not, the reason why) and details of any dietary supplements taken. The software also contained a serie of questions about usual eating habits (for example, type of milk or fat spread usually consumed) to facilitate coding.

Food and beverage records were returned from the field in *real time* to be coded by trained coders and editors. For this purpose, an *ad hoc* Central Server software/database was developed by IPSOS (Java/IE10 compatible) in order to be able to work in parallel with the verification process followed by the codification. Within this context, the software was prepared to receive the information from the field tablets every two seconds, and updated every 30 minutes. The Central Server contained different modules to verify the information at individual level but also according to the specific cycle; food weight and intakes; food codification and the assigning weight in grams. If for any reason, the terminal was unable to be connected to the network, the recorded information by the participant was saved, and resubmitted once the problem was solved. The innovative Central Server system allowed checking the different cycles, the participants records, which meant that possible incidents were able to be fixed in a very short period of time. Finally, 189,600 inputs (ingredients) were managed from the 2,009 participants, about 73 items per participant, and 24.3 food/beverages items per person/day as mean.

Coders attempted to match each food or drink item recorded in the tablet device with a food/portion code. For composite items which could be split into their component parts, each individual component was assigned. If an item had been recorded and there was no suitable code or there was insufficient detail to code the food, the entry was flagged as a query. Each food code is linked to appropriate portion size descriptors, such as a tablespoon for rice or pasta, which are then linked to the correct weight for that descriptor. So if a participant recorded/described their food using household measures, coders under dieticians-nutritionists checking would be able to select the appropriate portion size. If the portion size was described as a weight, the weight would be entered directly into the system. Where the coder could not resolve the food or portion consumed, the entry was flagged as a query for action by a researcher who had greater nutrition knowledge and experience. The dieticians-nutritionists assigned appropriate codes for all flagged food and portion codes and checked any other queries raised by the coders. In general, where details for the coding of foods were missing, formally agreed default codes were used. Where portion sizes were missing, an estimate was made using the same weight if the food was consumed on another dietary day, or a portion size consistent with the participant's usual consumption (e.g. small, medium or large), or an age-appropriate average portion.

For new products still not included in the ANIBES program, supermarkets or retail markets were visited or the manufacturer contacted to obtain information on nutrient content in order to decide whether a new food code was needed. This decision was based on nutritional composition compared to that of existing codes, as well as the frequency of consumption. If a new food code was required, the nutrient content was entered into the database. In the case of school meals, school caterers information about the nutrient content and portion size of dishes was considered. For homemade dishes where a recipe had been recorded, the ingredients were entered individually using the appropriate cooked food codes, and all the codes for the dish were allocated to a recipe food group according to the type of dish. The weight of each cooked ingredient was calculated using the raw weights recorded by the participant, a weight loss factor for the whole dish if possible, and the weight of the portion consumed.

Quality control

The quality control of the collected information was supervised by trained dieticians-nutritionists, according to the following protocol:

a) The same dietician-nutritionist was responsible for checking the food records included by the participant during the three-day dietary food record study.

b) The initial quality control was based on the photographs and descriptions sent by the participants, but also the brief description that was asked before/after each meal and/or intake. Special care was given to validate some variables such as ingredients, brands of the processed and ready-to-eat foods, portion size or culinary technique in order to obtain accurate information for further codification.

c) The final approval of the received information was given by a dietician-nutritionist and supervisor.

It is also of importance that the used software had an alarm-system where no records from the different three main meals were available.

At the start of the coding process, dieticians-nutritionists worked together with the coders checking the information from the coders and giving them individual feedback on their work (food and portion code entries). Portion code errors (selecting the wrong portion size descriptor or entering an incorrect weight) were more common than selecting the wrong food code. Where errors were found they were corrected. These checks ensured that error rates were monitored for all the coders working on the project and helped identifying any coding issues. All of the entries flagged as a query by the coders were categorized into different query types, such as food code or portion code not available in the VD-FEN Software, recipes, missing or insufficient detail to code food or portion. Initial checks were carried out to highlight any missing data fields, such as incomplete eating context or nutrient variables, followed by a feasibility check of the maximum and minimum portion sizes entered within each subsidiary food group. Final quality checking was performed using each participant's mean energy and nutrient intake (all reported nutrients) over the food and beverages diary record period (three days). Extreme intakes were considered from the mean and all entries in this region were checked against the diary. All errors found were corrected to their appropriate entry as reflected by the diary entry. Intakes were also calculated.

Intakes of energy and nutrients were calculated from the food consumption records using a special adapted VD-FEN 2.1 (*Programa de Valoración Dietética de la FEN, Dietary Evaluation Program from the Spanish Nutrition Foundation*) software for ANIBES Study. Data obtained from food manufacturers were also used, as was nutritional information provided on food labels, and food photographic atlas to assign weighing grams for portion sizes. All data were carefully evaluated before being incorporated into the VD-FEN ANIBES Database, that is briefly stratified as:

- Level 1 – 16 food and beverage groups
- Level 2 – 29 food and beverage subgroups
- Level 3 – 761 food and beverages entries
- Company and brand
- Culinary treatment
- Household measure (tablespoons, glasses, cups, plates); typical/most used portion sizes and recipes from Spain; or conventional units/measures (e.g. 1 yogurt, 1 apple piece, half tomato, 1 slice of bread, 1 soda can, 1 biscuit, butter portion, etc.)

Data cleaning

Once the data from the Tablet devices were coded and transferred into the ANIBES Database, a data cleaning process was necessary as follows:

<u>First data cleaning stage:</u> Participants were considered as fully eligible if after a cautiously review of the information, it was verified that the three days were recorded. Where registers were above or below the three-days established period, the following criteria was adopted:

– If a participant only had records from two or less days, he/she was considered as not valid and eliminated from the final sample.

– If a participant registered four or more days, valid data were for those three collected days corresponding to the specific cycle of the participant, but always under the same scheme: 2 working days + 1 weekend day.

Second data cleaning stage: According to the recorded information, participants were removed from the final sample if:

– Unexplained behavior in energy intake and large intraindividual variations between days mostly when compared to the 24-h dietary recall. Moreover, when the known meal pattern of the participant was 3-5 intakes per day, but missing data was clearly observed in the register (i.e. only breakfast and/or one meal per day), he/she was removed from the final sample.

– Extremely low energy intakes recorded:

  - Less than 500 kcal/day in two or three days of the period.
  - Less than 500 kcal/day in one day, and <800 kcal/d in the remaining days.

Third data cleaning stage: Participants were considered valid if they fulfilled the following criteria:

Having fulfilled previous data cleaning stages.
Having completed successfully both visits during the fieldwork.
If the participants had valid data on: weight, height, waist circumference.

Once all data (three-days food dietary record and 24-h dietary recall) had been verified, cleaned up, and approved by the dieticians-nutritionists, the ANIBES Database was developed. Calculation of energy and nutrient intakes was performed by the VD-FEN 2.1 *Dietary Evaluation Programme from the Spanish Nutrition Foundation*, mainly based on the Food Composition Tables (Moreiras et al, 15 ed, 2011)[30], with several expansions and updates.

Conclusions

Energy balance is a framework that can be used to understand the interplay between energy intake, energy expenditure and energy storage that determines body weight.

A better understanding of energy balance can help develop more effective strategies for reducing obesity rates in individuals and populations.

Energy balance is a dynamic rather than a static process, with manipulations of one component of energy balance potentially influencing other components of energy balance.

The strengths of the design, protocol and methodology used in the ANIBES Study to approach for the first time the EB in Spain are the representative national sample targeted, the broad age range included (9-75 years), the geographical distribution (inland plus islands), the successful logistics for the 128 sampling points or the innovative and first time used tools to measure dietary intake (tablet device for *real time* dietary record combined with a 24-h dietary recall) or physical activity level (validated questionnaire and accelerometer device). The main drawbacks were the difficulties for some participants to use the technologies employed, or the lack of seasonality for food collection or measuring physical activity level. However, considering the carefully designed protocol based on best evidence available and previous experience, the ANIBES study will contribute to provide valuable useful data to inform food policy planning, food based dietary guidelines development and other health oriented policies

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References

1. Hill, J.O.; Wyatt, H.R.; Peters, J.C. Energy balance and obesity. *Circulation*. 2012, 126, 126-32.
2. Morton GJ, Cummings DE, Baskin DG, Barsh GS, Schwartz MW. Central nervous system control of food intake and body weigh*t. Nature* 2006;443: 289–95.
3. Hill, J.O.; Wyatt, H.R.; Peters, J.C. Using the energy gap to address obesity: a commentary. *J. Am. Diet. Assoc*. 2009, 109, 1848 –1854.
4. Hill JO, Levine JS, Saris WHM. Energy expenditure and physical activity. In: Bray G, Bouchard C. eds. *Handbook of Obesity*. 2nd ed. New York, NY: Marcel Dekker, Inc; 2003:631– 654.
5. Galgani J, Ravussin E. Energy metabolism, fuel selection and body weight regulation. *Int J Obes (Lond)*. 2008;32(7):S109–19.
6. Blair, S.N. Physical inactivity: the biggest public health problem of the 21st century. *Br. J. Sports Med*. 2009, 43, 1-2.
7. Johnstone AM, Murison SD, Duncan JS, Rance KA, Speakman JR. Factors influencing variation in basal metabolic rate include fat-free mass, fat mass, age, and circulating thryroxine but not sex, circulating leptin, or triiodothyronine. *Am J Clin Nutr* 2005;82:941–8.

8. Hall KD. Predicting metabolic adaptation, body weight change, and energy intake in humans. *Am J Physiol Endocrinol Metab* 2010;298:E449–66.
9. World Health Organization. *Physical status: the use and interpretation of anthropometry;* WHO Technical Report Series 854, WHO, *Geneva, Switzerland,* 1995.
10. Donnelly JE, Blair SN, Jakicic JM, Manore MM, Ranking JW, Smith BK. American College of Sports Medicine. Position Stand: appropriate physical activity intervention strategies for weight loss and prevention of weight regain for adults. *Med Sci Sports Exerc*. 2009;41(2):459–71.
11. Hall KD, Sacks G, Chandramohan D, et al. Quantification of the effect of energy imbalance on bodyweight. *Lancet*. 2011; 378(9793):826–37.
12. Hall KD, Sacks G, Chandramohan D, Chow CC, Wang YC, Gortmaker SL, Swinburn BA. Quantifying the effect of energy imbalance on body weight change. *Lancet* 2011; 378:826–37.
13. Hall KD, Heymsfield SB, Kemnitz JW, Klein S, Schoeller DA, Speakman JR. Energy balance and its components: implications for body weight regulation. *Am J Clin Nutr.* 2012;95(4):989–94.
14. Heymsfield SB, Thomas D, Martin CK, et al. Energy content of weight loss: kinetic features during voluntary caloric restriction.*Metabolism*. 2012;61(7):937–43.
15. Mayer J, Purnima R, Mitra KP. Relation between caloric intake, body weight and physical work: studies in an industrial male population in West Bengal. *Am J Clin Nutr*. 1956; 4:169 –175.
16. Hill JO, Commerford R. Exercise, fat balance and energy balance. *Int J Sports Nutr*. 1996; 6:80 –92.
17. Hill, J.O.; Wyatt, H.R. Role of physical activity in preventing and treating obesity. *J. Appl. Phyisol*. 2005, 99, 765–770.
18. Wadden TA. Treatment of obesity by moderate and severe caloric restriction: results of clinical research trials. *Ann Intern Med*. 1993;13(suppl 2):91–93.
19. Dulloo AG, Jacquet J. Adaptive reduction in basal metabolic rate in response to food deprivation in humans: a role for feedback signals from fat stores. *Am J Clin Nutr*. 1998; 68:599–606.
20. Varela, G.; García, D.; Moreiras-Varela, O. *La Nutrición de los Españoles. Diagnóstico y Recomendaciones; Escuela Nacional de Administración Pública, Madrid,* 1971.
21. Varela, G.; Moreiras, O.; Carbajal, A.; Campo, M. *Encuesta de presupuestos familiares 1990-91; Spanish National Statistical Institute,* 1991; Vol I.
22. Varela, G.; Moreiras, O.; Carbajal, A.; Campo, M. *Encuesta de Presupuestos Familiares 1990-91. Estudio Nacional de Nutrición y Alimentación* 1991; *INE, Madrid,* 1995; Vol I.
23. Varela-Moreiras, G. La Dieta Mediterránea en la España actual. *Nutr Hosp*.2014,30(Supl. 2):21-28
24. Del Pozo, S.; García, V.; Cuadrado, C.; Ruiz, E.; Valero, T.; Ávila, J.M.; Varela-Moreiras, G. *Valoración Nutricional de la Dieta Española de acuerdo al Panel de Consumo Alimentario*; *Fundación Española de la Nutrición (FEN), Madrid,* 2012.
25. Agencia Española de Seguridad Alimentaria y Nutrición (AESAN). *Encuesta Nacional de Ingesta Dietética Española* 2011. Available at: http://www.aesan.msc.es/AESAN/docs/docs/notas_prensa/Presentacion_ENIDE.pdf
26. Serra-Majem, L.; Ribas Barba, L.; Aranceta-Bartrina, J.; Pérez-Rodrigo, C.; Saavedra Santana, P.; Peña- Quintana L. Obesidad en la infancia y adolescencia en España. Resultados del estudio enKid (1998–2000). *Medicina Clinica* 2003, vol. 121, no. 19, 725–732.
27. González-Gross, M.; Castillo, M.J.; Moreno, L.; Nova, E.; Gonzalez-Lamuño, D.; Perez-Llamas, F.; Gutiérrez, A.; Garaulet, M.; Joyanes, M.; Leyva, A.; Marcos, A.; and grupo AVENA. Alimentación y Valoración del Estado Nutricional de los Adolescentes Españoles (Proyecto AVENA). Evaluación de riesgos y propuesta de intervención. I. Descripción metodológica del estudio. *Nutr. Hosp*. 2003, 18, 15-27.
28. Ministerio de Sanidad, Consumo, Igualdad y Servicios Sociales. *Encuesta Nacional de Salud 2011-2012;* Ministerio de Sanidad, *Consumo, Igualdad y Servicios Sociales, Madrid,* 2013.
29. Booth, M.L.; Ainsworth, B.E.; Pratt, M.; Ekelund, U.; Yngve, A.; Sallis, J.F.; *et al*. International physical activity questionnaire: 12-country reliability and validity. *Medicine & Science in Sports & Exercise* 2003, 195(9131/03), 3508-1381.
30. Moreiras, O.; Carbajal, A.; Cabrera, L.; Cuadrado, C. *Tablas de composición de alimentos*, 15ª edición; Ed. Pirámide; Madrid, 2011.