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Applied nutritional investigation

Validation of a food frequency questionnaire in the assessment of dietary glycemic index, glycemic load, and protein intake in pregnant women with obesity

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A R T I C L E I N F O

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A B S T R A C T

Objectives: Studies suggest that diets with a low glycemic index and high protein are favorable in aiding weight loss and improving weight maintenance; however, methods to measure dietary intake are comprehensive both for the participant and the study staff. We aimed to validate the accuracy of the dietary glycemic index and protein intake assessed through a food frequency questionnaire against a 4-d weighed food record in Danish pregnant women with obesity.
Methods: A total of 31 pregnant women completed a 29-item food frequency questionnaire and a 4-d weighed food record with overlapping time periods. The women had a mean (± SD) age of 30.6 ± 3.9 y and a prepregnancy body mass index of 33.9 ± 3.5 kg/m^2. We evaluated the validity of the food frequency questionnaire by Bland-Altman plots and the Spearman correlation coefficient.
Results: The results of the validation study found good acceptance of the 29-item food frequency questionnaire. The mean intake of glycemic index, glycemic load, and protein intake of the 29-item food frequency questionnaire and the weighed food record correlated well, although intake data of the 29-item food frequency questionnaire tended to be lower. Spearman correlation coefficients had moderate to high correlations for glycemic index ($\rho = 0.73$; $P < 0.001$) and protein intake ($\rho = 0.70$; $P < 0.001$). A moderate correlation was found for glycemic load ($\rho = 0.55$; $P = 0.002$). There was no correlation for carbohydrates ($\rho = 0.21$; $P = 0.253$).
Conclusion: The results suggest no risk of bias between the two methods of assessment; hence, a 29-item food frequency questionnaire can be used to assess the mean glycemic index, glycemic load, and protein intake in pregnant women with obesity.

Introduction

Investigators have examined the effect of altering the quantity and quality of diets and have found that diets with a low glycemic index (GI) and glycemic load (GL) are favorable in aiding weight loss and improving weight maintenance [1,2]. Nutrition during the early evolving period in utero plays an important role in normal fetal growth and development, and new evidence concludes that reducing gestational weight gain by dietary interventions reduces the risk of adverse events during pregnancy among obese women [3]. The level of compliance during dietary interventions is crucial for evaluating the effect of the investigated dietary regimen. There are several methods for assessing dietary intake, including 24-h recall, historical food interviews, food frequency questionnaires

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(FFQs), and food diaries [4]. Weighed food records (WFRs) are considered the golden standard and are often used as a reference tool to validate more simple dietary assessment tools to be used in larger populations. WFRs are more comprehensive both for the participant and the study staff compared with an FFQ as the detailed registration requires highly motivated and literate participants and the staff must use a computerized program to calculate dietary records. Because of high feasibility and cost-effectiveness, the FFQ is widely used to assess dietary intake in larger interventions and population studies. The FFQ relies on a good memory compared with the WFR, and the FFQ is therefore prone for a higher risk of erroneous assessment. Individuals with obesity are likely to underreport energy and carbohydrate-rich foods using diet history [5] and investigations among pregnant women found FFQ more poorly correlated with food records among those who are overweight than among lean controls [6]. There are, to our knowledge, no studies investigating the validity of assessing GI, GL, and protein intake among pregnant women with obesity. The aim was to validate a 29-item FFQ in the assessment of dietary GI, GL, and protein intake in pregnant women with obesity.

Materials and methods

Participants

A total of 40 pregnant women with obesity, living in the greater Copenhagen area, were invited to participate in validating an FFQ developed for the Nordic populations. Of the enrolled 40 participants, only 31 completed all the days of registration, whereas 9 failed to complete. These 31 women completed an FFQ designed to assess the habitual diet during the previous month and a 4-d WFR spanning 3 weekdays and 1 weekend day. Height was measured to the nearest 0.5 cm using a wall-mounted stadiometer, prepregnancy weight was obtained by pregnancy journal (either self-recorded or doctors first weighing at ~7 wk gestation) and registered to the nearest 0.1 kg, and body mass index (BMI) was calculated as weight in kilograms divided by the square of the height in meters. The validation study was part of a large randomized controlled intervention study approved by the Ethics Committee of the Capital Region of Denmark (VEK:H-3–2013-119) and registered at Clinical Trials.gov (NCT01894139). The dietary assessments were performed from February 2015 through August 2017.

Weighed dietary assessment

A qualified clinical dietician developed the scheme for the 4-d WFR and instructed each participant individually in weighing and registering all information on the foods and drinks consumed and how to register the information in the scheme. Together with the scheme was an example of how to register and photograph typical foods and dishes in increasing sizes (e.g., bread in different thicknesses with different amounts of spreads on top, pasta Bolognese or stew, mashed potatoes, and also candy and cake in different serving sizes). The women were instructed to use either an electronic diet weight scale or use household measures or refer to a standardized photo if relevant to measure the amount of dietary consumption. Moreover, the women were instructed to specify the used method of preparation (e.g., boiling or baking) and the fat used (e.g., olive oil or butter), if any. At the return of the WFR, the clinical dietician reviewed the registrations immediately and resolved any uncertainties with the responding woman. In the case of stews or other casserole or oven dishes, the dietician obtained the recipes for accurate registration.

Food frequency questionnaire

The FFQ was a self-administrated questionnaire based on a standardized and validated questionnaire by Andersen and colleagues [7] and modified to include questions specifically intended to assess GI, GL, and protein intake. The women were instructed by a qualified clinical dietician on how to complete the 29-item FFQ based on food groups (e.g., "drinking dairy products" or "eating dairy products together with cereal or similar"). The average frequency of consumption could be 1 of 8, ranging from "once per month" to "4–5 times a day or more" of each food or beverage item where appropriate. Information on product specificities (e.g., type of yogurt, whole grain, or percentage of whole kernels) was specified and the frequency was given for each individual food product. The predefined FFQ item portion sizes were given as standard household (e.g., deciliter or tablespoon) or natural (e.g., glass or slice) units. The women were encouraged to register frequently foods not listed in the FFQ in a separate column for this specific purpose.

Dietary calculations

Daily dietary consumption registered in the FFQ was calculated by multiplying the frequency of the food item by the portion size stated or by a fixed portion size [8]. Daily dietary consumption of the WFR was based on registered quantities of specific food types.

Dietary data from the FFQ and WFR were divided into standardized food groups matching the FFQ questionnaire and based on estimates of average GI and carbohydrate content. The standardized food groups were built into an electronic program for nutritional calculation in Dankost Pro version 1.4.24.30 (Kraftvaerk FoodTech, Copenhagen, Denmark) and used to calculate the nutrient content of the food.

Dietary calculations of protein, vitamin D, and calcium consumption in the WFR were performed using Dankost Pro version 1.4.24.30, where data are derived from the Danish food composition tables (Frida Food Data, National Food Institute, Technical University of Denmark, Søborg, Denmark). Dietary calculations of protein, vitamin D, and calcium consumption in the FFQ were based on the described food groups in the electronic diet calculation program.

Dietary calculations of carbohydrate and GI values were obtained using the "International Tables of Glycemic Index and Glycemic Load Values: 2008," where data are based on studies using standardized methodology, and glucose was used as a reference, defining the GI reference value to 100 [9]. Because of differences in food products between Australia, the United States, and the Nordic countries (e.g., cereal and rye bread), we identified the most accurate; when multiple food products were recognized, we calculated the mean value and used this to obtain the most accurate GI values. We grouped food items with similar GI value and carbohydrate content (e.g., similar types of rye bread) and made the assumption of new products with similar content and method of preparation as a product with known GI value had equal GI values (e.g., yogurt with a new type of fruit). The total dietary GI was calculated as a weighed mean of the GI values of the carbohydrate-containing food groups according to both FFQ and WFR; the weighing was based on the proportion of the total carbohydrate content provided by each food group. GI was calculated using Excel (Microsoft Office Professional 2010; Microsoft, Redmond, WA). Dietary GL was calculated by multiplying the dietary GI value with the total dietary carbohydrate content and dividing by 100.

Statistics

The statistical analyses were calculated on all participant as one group. Because of non-normal distributions of measured values (visual assessment of histograms), the descriptive results are presented as mean ± SD and as median (25th and 75th percentiles). The relative agreement between the FFQ and WFR was assessed using Spearman ρ correlation.

Bland-Altman plots were performed to visually present the level of agreement between the two dietary assessment methods. The Bland-Altman plots presented the difference in the estimated mean GI, GL, protein intake, vitamin D, and calcium of the FFQ plotted against the mean dietary GI, GL, protein intake, vitamin D, and calcium reported in the WFR.

The statistical analyses were performed using the statistical program R version 3.6.1 [10].

Results

The 31 pregnant women had a mean (± SD) age of 30.6 ± 3.9 y and a pre-pregnancy BMI of 33.9 ± 3.5 kg/m^2. The women were in their second or third trimester, and completion of an FFQ took an average of 30 min. The two dietary assessment methods had a correlation in GI (ρ = 0.73; $P < 0.001$), GL (rho = 0.55; $P = 0.002$), protein intake (rho = 0.70; $P < 0.001$), vitamin D (ρ = 0.58; $P < 0.001$), and calcium (ρ = 0.65; $P < 0.001$) (Table 1). However, the correlation of GL between the short 29-item FFQ and the 4-d WFR was poorer than that of GI and protein. There was no correlation between the two methods for carbohydrates where the FFQ reported a lower amount of carbohydrates compared with 4-d WFR (184.6 ± 45.2 versus 204.3 ± 51.7; $P = 0.253$).

A Bland-Altman plot (Fig. 1A) was constructed to describe the agreement between the two methods for GI. The plot has a small negative mean difference between the FFQ and WFR, indicating that WFR tends to provide a higher estimate of GI consumed than FFQ. The average difference is −0.9 and the 95% CI for the average difference is −10.0 to 8.3. Most measurements are within the 95 % limits of agreement, and the regression analysis indicates the GI

Table 1
Daily intake assessed by food frequency questionnaire and 4-d weighed food diary and correlation between methods ($n = 31$)

	FFQ			Weighed food diary			Spearman correlation	
	Mean ± SD	Median	Q1–Q3	Mean ± SD	Median	Q1–Q3	Rs-value	*P* value
Glycemic index	49.7 ± 6.4	50.9	45.6–53.9	50.6 ± 5.7	51.5	46.7–54.2	0.73	< 0.001
Glycemic load	91.9 ± 25.4	92.3	76.1–102.5	105.6 ± 33.1	107.4	77.7–130.4	0.55	0.002
Carbohydrate (g)	184.6 ± 45.2	180.9	154.5–209.0	204.3 ± 51.7	204.0	165.1–245.1	0.21	0.253
Protein (g)	96.2 ± 31.0	84.7	75.3–116.8	100.3 ± 26.8	99.9	79.1–120.0	0.70	< 0.001
Vitamin D (μg)	3.8 ± 1.7	3.6	2.4–4.8	3.9 ± 2.6	2.9	2.0–5.2	0.58	< 0.001
Calcium (mg)	1374.0 ± 714.6	1191.0	945.5–1768.5	1294.0 ± 401.1	1279.0	1028.0–1456.0	0.65	< 0.001

FFQ, food frequency questionnaire; Q1–Q3, 25th–75th percentiles.

values of the FFQ are comparable with those identified by WFR ($P < 0.001$) (Fig. 1B).

Figure 2A illustrates a small negative mean difference between the FFQ and WFR of −4.1 g (95% CI, −55.6 to 47.3). This indicates that WFR tends to provide a higher estimate of protein consumed than FFQ; however, most measurements are within the 95% limits of agreement, and the regression analysis indicates that protein intake values of the FFQ are comparable with those identified by WFR ($P < 0.001$) (Fig. 2B).

When comparing FFQ and WFR on GL, there was a small negative mean difference between the FFQ and WFR of −13.8 (95% CI, −72.3 to 44.8) (Fig 3A). This indicates that WFR tends to provide a higher estimate of GL compared with FFQ; however, most measurements are within the 95 % limits of agreement. Moreover, the regression analysis of GL finds that the FFQ was comparable with WFR ($P = 0.002$) (Fig. 3B).

There was a small negative mean difference between the FFQ and WFR in vitamin D intake of −0.1 μg (95% CI, −4.4 to 4.2) and a positive mean difference for calcium of 79.6 mg (95% CI, −1158.5 to 1317.7) (Figs. 4A, 5A). This indicates that WFR tends to provide a higher estimate of vitamin D and a lower estimate of calcium compared with FFQ; however, most measurements are within the 95% limits of agreement. Moreover, the regression analysis of vitamin D intake and calcium intake finds that the FFQ was comparable with WFR ($P < 0.001$; $P < 0.001$), respectively (Figs. 4B and 5B).

Discussion

The present study found a short 29-item FFQ valid to assess dietary GI and protein intake compared with a 4-day WFR on when reported by pregnant women with obesity. Even being significant, the correlation of GL assessed by FFQ and WFR was too poor to be recommended.

The Bland-Altman plots for GI and protein intake indicated no risk of bias. The results find that the FFQ was useful in measuring and comparing GI and protein intake among pregnant women with obesity. A study comparing a 131-item FFQ in relation to two 3-d food records focusing on dietary GI and GL found the 131-item FFQ valid on carbohydrate exposure variables in epidemiology studies [11]. Moreover, a study comparing 58-item GI-FFQ with the general 183-item FFQ and a 2-d, 24-h recall found that the 58-item GI-FFQ found moderate to good relative validity for GI [12].

Many validation studies have been carried out, yet the present study provides useful information to support population health monitoring and may be used in the assessment of GI and protein intake in larger interventions (e.g., limiting gestational weight gain

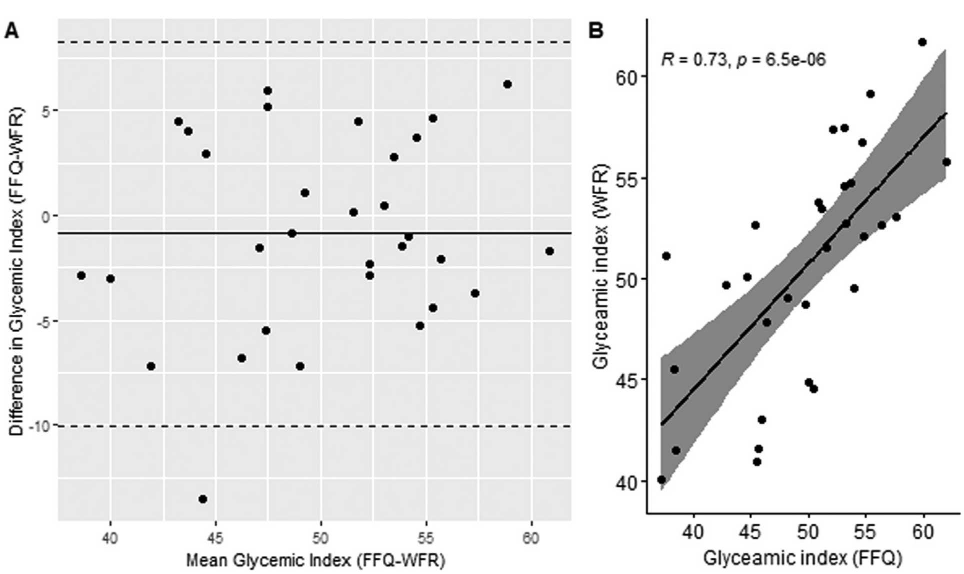

Fig. 1. (A) Bland-Altman plot assessing the validity of the FFQ versus the 4-d WFR for glycemic index among obese pregnant women ($n = 31$). The middle line indicates the mean difference; upper and lower dashed lines indicate borders based on 95% limits of agreement. (B) Spearman correlation model assessing the correlation between FFQ and the 4-d WFR for glycemic index among obese pregnant women ($n = 31$). FFQ, food frequency questionnaire; WFR, weighed food record.

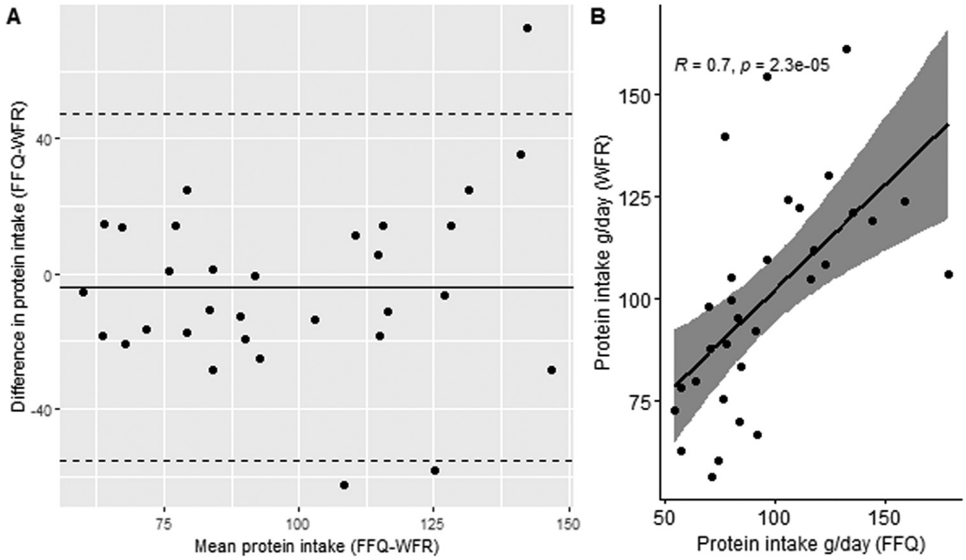

Fig. 2. (A) Bland-Altman plot assessing the validity of the FFQ versus the 4-d WFR for protein intake among obese pregnant women (n = 31). The middle line indicates the mean difference; upper and lower dashed lines indicate borders based on 95% limits of agreement. (B) Spearman correlation model assessing the correlation between FFQ and the 4-d WFR for protein intake among obese pregnant women (n = 31). FFQ, food frequency questionnaire; WFR, weighed food record.

among pregnant women with obesity). In our study, we used a short 29-item FFQ based on food groups, which only took an average of 30 min to answer. Keeping detailed food records or undertaking 24-h recalls of dietary consumption can be burdensome for the participants and resource intensive for researchers, which is why it if appealing to have a simpler and shorter tool.

One of the limitations of the study is the small sample size available for the analysis with complete data from the two dietary assessments in 31 women. This limits the implication of investigating the validity across characteristics, such as age and BMI, which is important, because we know self-reported dietary assessment methods have been reported to be associated with variables, such as age, sex, and BMI, all of which can generate reporting bias [13]. Consequently, further research encompassing a more extensive cohort will provide the capacity to examine the generalizability of the 29-item FFQ findings across diverse characteristics, such as age and BMI. However, in our study we used the same participants with almost identical characteristics for FFQ and WFR, reducing the risk of bias. Second, these data do not include validation of daily fat intake or daily energy intake, limiting the opportunity to use this short 29-item FFQ in studies assessing these dietary components.

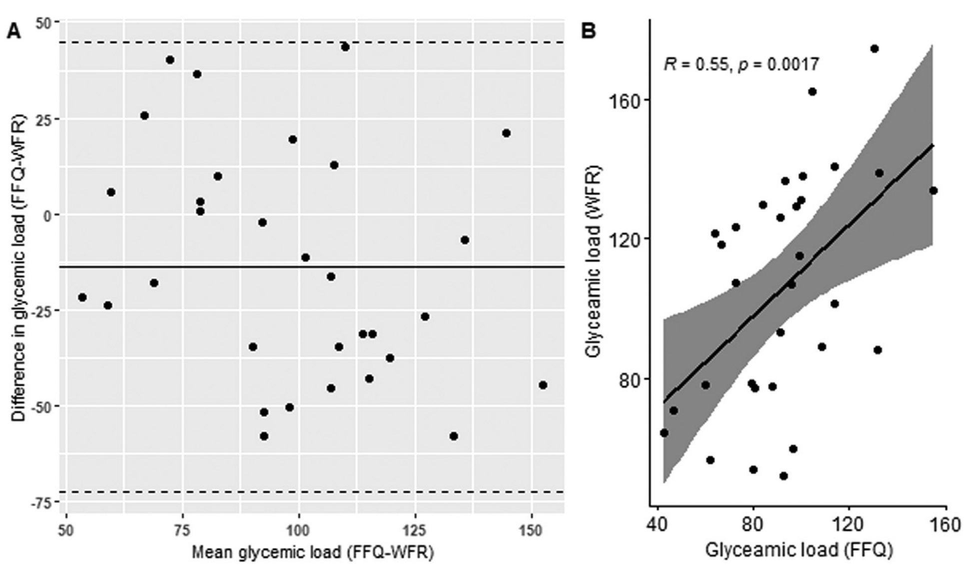

Fig. 3. (A) Bland-Altman plot assessing the validity of the FFQ versus the 4-WFR for glycemic load among obese pregnant women (n = 31). The middle line indicates the mean difference; upper and lower dashed lines indicate borders based on 95% limits of agreement. (B) Spearman correlation model assessing the correlation between FFQ and the 4-d WFR for glycemic index among obese pregnant women (n = 31). FFQ, food frequency questionnaire; WFR, weighed food record.

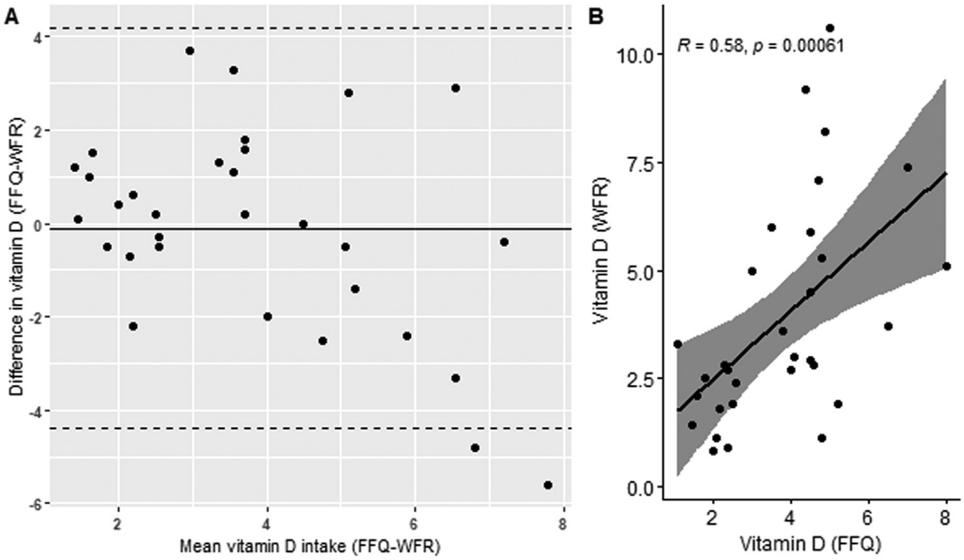

Fig. 4. (A) Bland-Altman plot assessing the validity of the FFQ versus the 4-d WFR for vitamin D intake among obese pregnant women ($n = 31$). The middle line indicates the mean difference; upper and lower dashed lines indicate borders based on 95 % limits of agreement. (B) Spearman correlation model assessing the correlation between FFQ and the 4-d WFR for vitamin D intake among obese pregnant women ($n = 31$). FFQ, food frequency questionnaire; WFR, weighed food record.

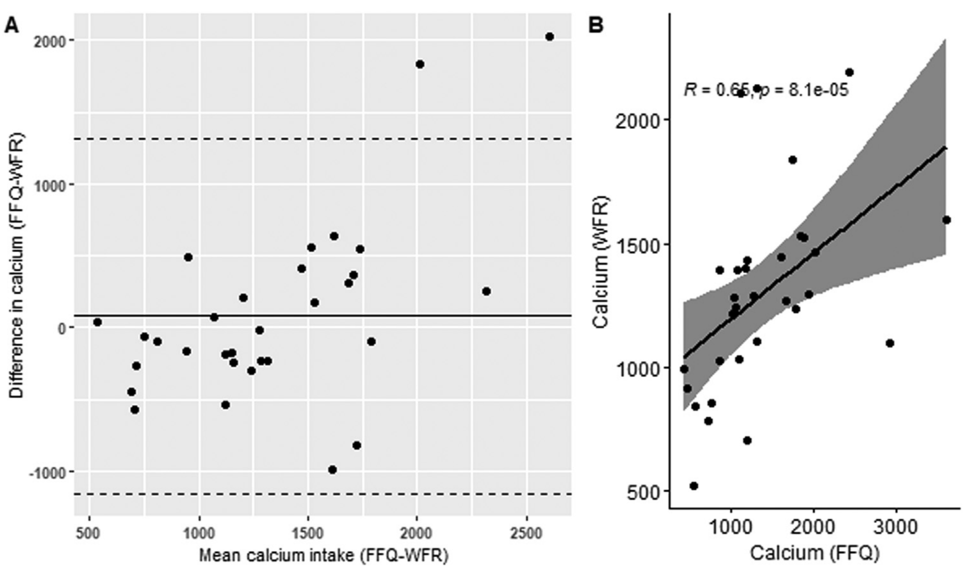

Fig. 5. (A) Bland-Altman plot assessing the validity of the FFQ versus the 4-d WFR for calcium intake among obese pregnant women ($n = 31$). The middle line indicates the mean difference; upper and lower dashed lines indicate borders based on 95% limits of agreement. (B) Spearman correlation model assessing the correlation between FFQ and the 4-d WFR for calcium intake among obese pregnant women ($n = 31$). FFQ, food frequency questionnaire; WFR, weighed food record.

Conclusion

To our knowledge, this is the first study validating a short 29-item FFQ with a 4-d WFR among pregnant women with obesity. The results on GI and protein intake indicated no risk of bias between the two methods of assessment; hence, the short 29-item FFQ is a reliable assessment tool to assess daily GI and protein intake in pregnant women with obesity.

Declaration of Competing Interest

None.

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The Italian IV SCAI dietary survey: Main results on food consumption

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ABSTRACT

Background and aims: The food consumption surveys, conducted for over 30 years by the CREA Research Centre for Food and Nutrition, are the most reliable source of data to evaluate the food consumption intake and dietary patterns of the Italian population. The fourth and most recent survey (IV SCAI 2017–2020), was carried out as part of the pan-European framework 'EU Menu', according to the harmonized methods recommended by European Food Safety Authority (EFSA). The current paper aims to present its main results in terms of food group consumption.

Methods and results: The sample of IV SCAI was stratified by geographical areas and included 1969 individuals aged 3 months to 74 years living in Italy. Dietary assessment was based on food diaries for children, and 24h recalls for adolescents, adults, and elderly, for both techniques on two non-consecutive days. The most consumed food groups were: *Milk* and *Cereals*, followed by *Fruit*, *Vegetables*, and *Meat*. At the subgroup level, bread was the most consumed cereal product in terms of quantity (70 g/day), followed by pasta (79 % of consumers; 49 g/day). Only 39 % of individuals had an adequate fruit and vegetable consumption according to the latest World Health Organization (WHO) recommendations, although this percentage increased in adults and the elderly (43 %, and 73 % respectively). Consumption of red and processed meat was also not in line with international recommendations, being slightly higher mainly in adults and adolescents with a mean consumption of 83 g/day and 100 g/day respectively, compared to the WHO recommendation not to exceed 70 g/day.

Conclusion: The detailed dietary data collected in IV SCAI are a fundamental evidence platform supporting public health programs, a reliable reference to guide nutritional policies and monitoring diet in the coming years.

1. Introduction

National food consumption studies are essential for evaluating nutritional quality, developing food based dietary guidelines and nutrition recommendations, making decisions regarding nutrition policy, health education interventions and estimate dietary exposure to chemicals. Adequate nutrition is one of the pillars of public health and before formulating and implementing effective intervention programmes to improve nutrition at the population level, it is important to know the nutritional status of the target groups [1]. In addition, food consumption data are also inextricably linked to the assessment of the environmental impact and sustainability of the different dietary patterns [2].

In this context, the Council for Agricultural Research and Economics (CREA) - Research Centre for Food and Nutrition has carried out four nationwide individual dietary surveys, in the last forty years: "INN 1980–84" [3], "INN-CA 1994–96" [4]," INRAN-SCAI 2005–06" [5], and the latest fourth Italian Food Consumption Survey (IV SCAI) from 2017 to 2020. Over the years, the methodology varied from the 7-days household food inventory method weighed by scales (INN 1980–84) to the individual 7-days weighed (by scales) food diary combined with the 7-days food inventory (INN-CA 1994–96), and, finally, to the 3-days food diary (INRAN-SCAI 2005–06). In all cases, household-level data randomly drawn from the population were used to estimate individual dietary data. Methodological differences between the studies make these data only partially suitable for cross-country comparison, thus limiting

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harmonized analyses of dietary exposure on a pan-European level and introducing uncertainties into the resulting assessments [6]. The experience of Concise Database [7] provided an example of the first available European database on food consumption aggregated data from individual dietary surveys carried out at national level. Since then, the idea of harmonized and detailed food consumption data at the European level and nationally representative diet and nutrition surveys, has been widely recognized as essential to improve the validity and reliability in assessing dietary patterns and intakes in populations and informing policy decisions [8,9]. Regular update of food consumption data is also essential. The fourth National Food Consumption Survey (IV SCAI) was conducted in compliance with the EU Menu methodology recommended by EFSA [10]. The aim of the EU Menu initiative was to collect food consumption data at EU level covering different age classes (at least two age groups were mandatory, such as from 3 months to 9 years and 10–74 years) across all Member States, using methods allowing the comparison of the results. It also recommended to use either a Computer Assisted Personal Interview (CAPI) [11] or a data entry system for diaries [12] methodology in the food data collection by validated national dietary recall software tools with a high level of quality assurance to provide reliability and harmonized data collection [10]. EFSA methodology also allowed capturing detailed food descriptors, such as the type of packaging material (glass, can, plastic etc.), cooking method (grilled, boiled, baked) and all those useful for the exposure assessment, and the collection of participants' anthropometric data [6,10].

The availability of this type of data collected at the individual level in different population groups is crucial to characterize food consumption patterns. Describing and analysing nutritional practices and dietary intake, especially in childhood, can prevent long-term health effects such as increase the risk of several non-communicable diseases [13–17].

Moreover, knowledge of national food consumption data is crucial to the formulation of the Italian Dietary Guidelines [18,19] and the drafting of the Reference Intake Levels of Nutrients and Energy for the Italian population (LARN) [20], as well as identifying areas for intervention in nutrition education and public health campaigns and providing support for the country's agri-food policy.

The purpose of the present work is to present the main results, in terms of food consumption, of the two dietary surveys included in the IV SCAI study, specifically, the IV SCAI children's survey and the IV SCAI adult's survey, to provide key information for future food policies.

2. Methods

The Italian IV SCAI study consisted of two cross-sectional surveys on food consumption carried out by CREA Research Centre for Food and Nutrition between June 2017 to January 2020. The methodology was developed to comply as closely as possible with EFSA requirements [10, 21,22], aimed to harmonize food consumption data across the Member States of the European Union. A detailed description of the study design, sample and survey protocol is reported elsewhere [23,24]. The main features are summarised below.

2.1. Study design

The target population included individuals living in Italy aged 3 months to 9 years for the children's survey, and 10–74 years for the adult's survey.

The two samples were stratified by sex and geographical areas (North-West, North-East, Centre, South & Islands) with a subsequent establishing of sampling points, where recruited fieldworkers were placed.

The age groups involved, according to EFSA's EU MENU guideline for exposure assessments, were infants (3–11 months), toddlers (1–2 years), other children (3–9 years) for the children's survey, and adolescents (10–17 years), adults (18–64 years) and the elderly (65–74 years) for the adult survey; EFSA also recommended including at least 260 participants in each of the six age groups.

In both surveys, the study subjects were evenly distributed over the four seasons and weekdays (71 %) and week-end days (29 %) to capture inter-seasonal variability in dietary patterns and day-to-day consumption fluctuations; special periods such as Christmas and Easter were excluded. Institutionalized subjects, such as those living in boarding schools, retirement home, prison, etc., which correspond to 0.6 % of the population, were not recruited [25].

All enrolled subjects signed written informed consent, and the study was conducted in accordance with the Declaration of Helsinki [26] and approved by the Ethics Committee of "Lazio 2" (Rome, Italy, protocol code 106 872/2016, October 19, 2016) and by the Ethics Committee of National Institute of Health (Rome, Italy, protocol code AOO-ISS 0028469, September 24, 2018).

2.2. Dietary intake data collection

Dietary assessment was based on two non-consecutive 1-day food diaries for children aged 6 months to 9 years, and two 24-h dietary recalls for participants aged 10–74 years, separated by at least 15 days to ensure that information best resembled usual dietary intake. Two paper-based food diaries were developed for different age classes: 3–11 months and 1–9 years, which differed mainly in the food consumption section. In the format for infants (3–11 months), a section related to the preparation of each feeding with infant formula was added, i.e., amount prepared, and quantity leftover and the type of water used for formula in powered milk preparation. In the children's food dairy format (1–9 years), the consumption day was divided into seven eating occasions including three main meals (breakfast, lunch, dinner) and four between-meal snacks (before breakfast, between breakfast and lunch, between lunch and dinner, after dinner). The child's parents or caregivers were trained to report all liquid and solid foods consumed by the children, including food supplements and/or medicines containing nutrients. They were also instructed of detailing the food/recipe including cooking methods, storage, specific formulation, etc., and brand names where available.

The 24-h recall technique was used for the adult population (10–74 years), through the Computer Assisted Personal Interview (CAPI), developed according to the Multi-Pass protocol following EFSA guidance [10], to facilitate an accurate and complete recall and overcome respondents' memory limitations. The software allowed the input of food items, recipes, beverages and food supplements consumed during the survey days in accordance with the 24h recall rules (e.g. applying the "Multiple-Pass method"). During data entry, it was possible to automatically describe, search and quantify each item using the quantification methods (e.g. a validated picture, standard portions based on real weights and similar). The interviewer asked the respondent to recall the foods, beverages and any food supplements consumed on the preceding day, according to the type of meal, time and place of food consumption occasion, food name, whether it was a recipe or not, and amount consumed. Additionally, questions were asked about the preparation process, qualitative information (fat/sugar/salt-related info, etc.), the use of any sweetening agents, fortified foods, and lastly the packaging material.

Food portions consumed were estimated using pictures of food servings and household measures (e.g., glasses, cups) or expressed directly in weight/volume or standard units (such as commercial food portions). Two picture books were developed specially for children and adults. They included a selection of photographs from the PANCAKE study [27] and a selection of pictures extracted from other validated food atlas, namely the Italian version of GloboDiet picture book and the Istituto Scotti Bassani atlas (only for bread) [28–33].

The data entry of dietary information was performed using the software 'FoodSoft 1.0' developed by CREA Research Centre for Food and Nutrition and continuously updated [5,34,35]. In 2014, this tool underwent an EFSA ring trial which aimed to identify and evaluate the variation in food consumption data collected through different methodologies (e.g. different software, procedures and connected databases) in use in Europe [12]. The current online version includes two modalities of data entry through the "Food diary" and "24-h recall" and a "data management" features. The system uses different databases that have been continuously updated during the pilot study and field work: portion sizes, unit of measures, nutritional food composition in macro- and micro-nutrients (in total 36 nutrients of which 6 minerals and 10 vitamins). The nutrient database is complete for all the nutrients content for each food items, in case of missing value the best value was estimated [36–38]. The food list was largely composed of foods consumed in the INRAN-SCAI 2005–06 [5], which to date includes 3245 food items (2001 main foods, 1244 synonyms), 1523 recipes (1267 main dishes and 256 synonyms), and 439 dietary supplements. Synonyms for foods and recipes have been created to facilitate accurate identification during data entry, allowing for different popular and regional names. All foods, recipes, and food supplements were classified according to the FoodEx2 system [36,37], to be incorporated in the EFSA Comprehensive Database. However, the results presented here followed a different food classification.

2.3. Anthropometric characteristics and background questionnaires

During the first scheduled meeting, anthropometric data (body weight and length/height) were either self-reported and measured at the respondent's home or in the doctor's office, by trained interviewers using standardized procedures according to WHO recommendations [39] (further details in Refs. [23,24]). Height was measured to the nearest 0.1 cm by a stadiometer (SECA 214, Hamburg, Germany), while body weight was recorded to the nearest 50 g using an electronic scale (SECA 872TM, Hamburg, Germany). For children less than two years old, recumbent length was measured to the nearest 0.1 cm using a length measurement board and their weight was calculated by the difference between the weight of the caregiver holding the child and the caregiver's weight alone. Adolescents, school age children and infant were classified according to BMI age- and sex-specific z score cut-off points proposed by WHO [40] for 5–19 years, using WHO AnthroPlus software [41]. For adults and elderly, the BMI cut off points applied are those suggested by WHO [42] (underweight: BMI<18.50; normal: 18.50≤BMI<25.00; overweight: 25≤BMI<30.00; obese: BMI≥30.00).

The background questionnaires on socio-demographic characteristics were also designed following the guidelines for a general questionnaire based on the Pilot study for the Assessment of Nutrient intake and food Consumption Among Kids in Europe (PANCAKE) project [22] and on the Pilot study in the view of a Pan-European Dietary Survey (PAN-EU) project [21].

2.4. Interviewers

In the fourth national study on individual food consumption (IV SCAI), data collection was carried out by paediatricians, biologists, nutritionists, and dietitians specially trained to acquire specific skills. A training course was created to select motivated professionals, reduce drop-out rates and build a highly-skilled professional community. The aim was to train experts in the use of tools and techniques for food consumption surveys conforming to European standards, targeting age groups from 3 months to 9 years and 10–74 years [23,24].

Detailed information regarding the organisation of the above training path and the results achieved can be found elsewhere [43,44].

2.5. Statistical analyses

Food intakes at individual level, as mean of the two days of the survey, were described by means, Standard Deviation (SD), medians, Interquartile Range (IR) and high percentiles P90 and P95 stratified by sex and age classes. The Kruskal Wallis test was employed to compare the distribution of the 15 food groups across age groups. All analyses were carried out using sample weights that reflect the Italian population in 2019 for the corresponding age groups.

Statistical analysis was performed using SAS software, version 9.4 (SAS Institute, Inc.; Cary, NC).

3. Results

The national consumption survey was conducted on 2028 subjects, specifically 825 children aged between 3 months and 9 years and 1203 individuals aged between 10 and 74 years, all recruited from the resident population. The number of food diaries and 24-h recalls was 3997. Fifty-nine subjects (2.9 %) were excluded by the analysis because they reported only one survey day; specifically, fourteen children did not complete the second day of food record as well as forty-five adults missed the second 24-h recall, respectively.

Weekdays (Monday through Friday) accounted for 73 % of all survey days, slightly more than 5/7. The distribution among seasons, 28 % in autumn, 25 % in winter, 18 % in spring and 29 % in summer, was uneven due to the interruption of the survey during the COVID-19 pandemic (especially during the lockdown established by the Italian government in Spring 2020).

Data analysis was conducted on 1969 participants aged 3 months to 74 years who completed two-days food records or 24h recall interviews. The distribution of individuals in the main geographic areas (19 % North-East, 27 % North-West, 20 % Centre, and 34 % South & Islands) was representative of the Italian population [45] as was the sex rate, 48 % male, which confirmed the prevalence of females as in most European countries. The 90 % of the total sample declared they did not follow specific diet, while 0.8 % adopted a vegetarian diet, 1.4 % a slimming diet and 3.7 % reported special diet due to health conditions such as celiac disease, diabetes and allergy. Conversely, 4.1 % of the sample did not specify their diet. The main characteristics of the participants in both surveys, in terms of mean of energy intake, height, weight and Body Mass Index (BMI), are shown in Table 1 by age groups and sex. Infants under 1 year were divided into two age classes, 3–6 months, and 7–11 months, and not by sex. The energy intake of female in all age classes was significantly lower than that of males.

The percentage distribution of energy intake between meals (children under 1 year old of age were excluded) (Fig. 1) was higher for adults and the elderly in main meals, while for younger age groups, the percentage of energy of snacks was close to that of main meals.

The mean value of BMI in adult males was significantly higher than that in females, so is the prevalence of overweight. Out of whole sample, the percentage of obese was 11.8 %, while that of overweight was 22.6 % and that of thinness was 1.6 %.

The South & Islands had the highest percentage of obese (5.7 %) and overweight (9.4 %), followed by the Centre with 2.1 % and 4.5 % respectively. The results of the average daily intakes for the main food groups consumed by individuals aged ≥3 years are in Table 2, while results in terms of food subgroups by total population (n = 1969) and consumers only, are in Table 3. For infants aged 3–6 months and 7–11 months, daily average consumption is shown, without sex distinction, in the supplementary material (Tables S1 and S2). The individual daily consumption results for the remaining age groups by sex of the total population and of consumers only can be found in the supplementary material (Tables S3–S12). For an accurate interpretation of the data, Appendix B contains a list of major foods classified in each subcategory together with a list of the most frequent minor ingredients of composite foods belonging to other categories.

Food group means show that 12 out of 15 food groups differed significantly between ages (Table 2). Specifically, *Alcoholic beverages and substitutes* were predominantly consumed by adults and elderly (about 114 g/day and 113 g/day respectively) with significantly higher amount compared to adolescents (9.1 g/day with 34 male and 33 female who declared their consumption); the age group 10–17 years reported a

Table 1
Mean energy intake and physical characteristics of the studied sample in the IV SCAI Study by age classes and sex.

			Energy (kcal)	Energy (MJ)	Weight (kg)	Height (cm)	BMI (kg/m^2)	BMI class (%)			
Sex	Age groups (y)	n	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Thinness	Normal	Overweight	Obese
Male	1–2	162	1134 (273.3)	4.7 (1.1)	13.2 (2.0)	89.1 (6.9)	16.6 (1.7)	3.5	63.8	23.4	9.4
	3–9	168	1546 (410.1)	6.5 (1.7)	23.9 (9.0)	117.0 (15.1)	17.0 (3.1)	1.2	58.5	22.1	18.2
	10–17	138	2219 (573.6)	9.3 (2.4)	58.4 (14.3)	165.2 (13.7)	21.2 (3.7)	0.9	86.8	9.8	2.5
	18–64	346	2273 (563.8)	9.5 (2.4)	80.7 (14.2)	176.4 (6.9)	25.9 (4.4)	0.2	49.0	37.8	12.9
	≥65	65	2138 (619.4)	9.0 (2.6)	81.6 (13.9)	169.3 (6.6)	28.4 (4.1)	0.0	19.2	52.8	28.0
Female	1–2	160	1085 (241.4)	4.5 (1.0)	12.5 (2.1)	87.7 (7.1)	16.2 (2.0)	0.4	75.4	17.3	6.9
	3–9	171	1414 (331.2)	5.9 (1.4)	23.9 (8.1)	117.7 (13.8)	16.8 (2.9)	2.0	63.7	21.2	13.2
	10–17	138	1780 (463.9)	7.5 (1.9)	54.8 (13.1)	159.5 (8.5)	21.4 (4.2)	0.0	90.5	6.8	2.7
	18–64	380	1719 (402.7)	7.2 (1.7)	64.2 (13)	162.9 (6.2)	24.2 (4.8)	5.1	63.1	19.7	12.2
	≥65	91	1633 (429.2)	6.8 (1.8)	69.5 (15.6)	157.6 (7.5)	28.1 (6.7)	0.8	42.0	28.0	29.2
Total	3-6 (months)	26	777 (227.7)	3.3 (1.0)	7.8 (1.5)	66.9 (4.0)	17.2 (2.3)	2.2	78.6	10.0	9.2
	7-11 (months)	124	929 (229.5)	3.9 (1.0)	9.4 (1.2)	73.8 (3.3)	17.3 (1.7)	0.0	77.1	16.0	6.9
	1–2	322	1109 (258.7)	4.6 (1.1)	12.8 (2.1)	88.4 (7.0)	16.4 (1.8)	2.0	69.5	20.4	8.1
	3–9	339	1479 (377.8)	6.2 (1.6)	23.9 (8.5)	117.4 (14.4)	16.9 (3.0)	1.6	61.1	21.7	15.6
	10–17	276	2000 (566.0)	8.4 (2.4)	56.6 (13.8)	162.4 (11.8)	21.3 (3.9)	0.5	88.7	8.3	2.6
	18–64	726	1980 (559.3)	8.3 (2.3)	72.0 (15.9)	169.2 (9.4)	25.0 (4.7)	2.8	56.5	28.2	12.5
	≥65	156	1843 (569.8)	7.7 (2.4)	74.6 (16.0)	162.5 (9.1)	28.2 (5.8)	0.5	32.5	38.4	28.7

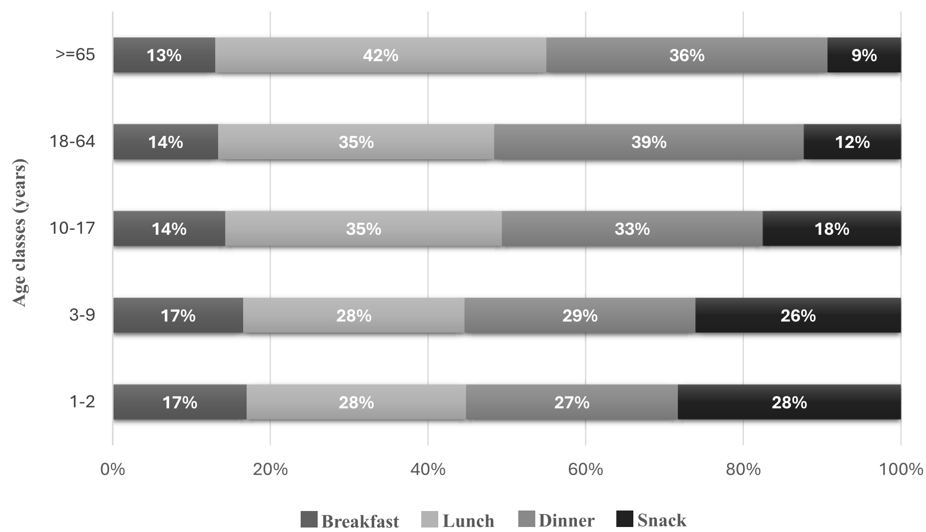

Fig. 1. Percentage distribution of Energy intake between meals by age classes

significantly higher consumption (267.6 g/day) of *Cereals, cereal products and substitutes* than other age classes. It should also be noted that the intake of males (304.2 g/day) was remarkably higher than that of females (231.1 g/day) regardless of age group (see supplementary materials). At the subgroup level, bread was the most consumed cereal product in terms of quantity, followed by pasta, which was the most used by 79 % of consumers (Table 3). The mean intake of *Fish, seafood and their products* show that the younger age classes consumed significantly less than the older ones. The intake of *Fruit, fresh and processed* and *Vegetables, fresh and processed*, increased with age. *Fruit* mean amount was significantly different between age classes, and *Vegetable* consumption of elderly and adults was significantly different compared to the younger subjects. *Meat, meat products and substitutes* were consumed by 92 % (refer to Table 3) of individuals and the mean intake at population level was 99.8 g/day. As expected, adolescents reported a significantly greater amount (143.1 g/day) than the other age classes. At the subgroup level, poultry and beef mean consumption was highest compared to the other types of meat (30.9 g/day and 30.5 g/day respectively). The major proportion of consumers was found for the subcategory *Ham, salami, sausages and other preserved meats, excl. offal* (59 %), but the highest daily consumption, in consumers, was reported for the subcategory *Other meat, not preserved, excl. offal* (76.6 g/day). Only nineteen subjects declared to follow a vegetarian diet during the survey and only ten subjects consumed meat substitutes (e.g. seitan and soya hamburger) among this category.

The food group largely consumed in terms of amount was *Milk, milk products and substitutes* with 237 g/day, and its consumption decreased with age since adults and the elderly reported significantly lower intake than adolescents and children. Subgroup level analysis showed an increase in cheese (from 22.2 g/day in preschool children to 48.3 g/day in adults, data not shown) and a decrease in milk consumption (from 179.6 g/day in preschool children to 85.9 g/day in adults, data not shown) up to the adult age group, while in the elderly both subgroups decreased (data not shown).

Olive oil was the most consumed fat with 98 % of consumers, followed by other vegetable oils. The mean intake of water and non-alcoholic beverages increased with age up to 1693.9 g/day for adults, and significantly decreased for the elderly. The most consumed beverage was bottled water, with 79 % of consumers.

Among 3 to 6 months-old, the consumption of breast milk was 567 g/day with a percentage of consumers equal to 62 % which decreased to 47 % in infants between 7 and 11 months, and further diminished to 10 % in toddlers, in both sexes (see supplementary material, Tables S1–S4). Fewer than half (41 %) of infants between 7 and 11 months recorded

Table 2
Mean intake (g/day), standard deviation (SD), median and interquartile range (IR) of food groups by age classes.

Food groups		Age classes							
		3-9 y (n = 339)		10-17 y (n = 276)		18-64 y (n = 726)		≥65 y (n = 156)	
	p^{a}	Mean (SD)	Median (IR)	Mean (SD)	Median (IR)	Mean (SD)	Median (IR)	Mean (SD)	Median (IR)
Cereals, cereal products and substitutes	<0.0001	182.1^{a} (70.6)	177.5 (91.5)	267.6^{a} (106.6)	258.4 (120.9)	239.1^{b} (101.6)	225.7 (125.6)	218.5^{b} (92.6)	208.0 (118.9)
Vegetables, fresh and processed	<0.0001	85.7^{a} (69.0)	70.5 (82.2)	145.1^{b} (105.2)	112.7 (141.5)	213.1^{c} (133.9)	190.5 (168)	241.4^{c} (141.6)	232.8 (185.9)
Potatoes, tubers and their products	0.0219	27.3 (36.1)	12.3 (39.9)	41.6^{a} (60.0)	15.0 (61.5)	45.9 (66.5)	5.0 (74.2)	32.2^{b} (58.5)	0.0 (41.8)
Pulses	0.469	7.3 (16.8)	0.0 (7.2)	9.1 (21.5)	0.0 (6.3)	10.8 (25.4)	0.0 (8.8)	10.7 (23.9)	0.0 (10.4)
Fruit, fresh and processed	<0.0001	139.1^{a} (121.5)	116.8 (43.3)	146.4^{a} (139)	117.0 (176.5)	193.6^{b} (157.8)	165.0 (205.4)	310.4^{c} (153.9)	295.7 (159.5)
Meat, meat products and substitutes	<0.0001	81.9^{a} (52.7)	78.9 (71.5)	143.1^{b} (103.8)	108.1 (114.9)	124.2^{c} (99.0)	107.9 (126.0)	97.6^{a} (86.6)	86 (115.6)
Fish, seafood and their products	<0.0001	23.1^{a} (38.2)	0.0 (37.7)	29.5^{a} (50.6)	0.0 (40.7)	46.7^{b} (68.5)	8.6 (78.0)	45.9^{b} (69.3)	9.0 (79.7)
Milk, milk products and substitutes	<0.0001	218.8^{a} (152)	205.5 (91.5)	203.7 (136.6)	196.0 (178.0)	175.0^{b} (125.0)	166.0 (183.0)	173.8^{b} (118.0)	178.9 (206.1)
Oils & Fats	<0.0001	19.6^{a} (10.1)	18.9 (12.9)	28.9^{b} (16.5)	25.8 (18.4)	32.3^{c} (16.4)	29.8 (19.1)	30.7^{b} (15.2)	28.2 (18.2)
Eggs	0.1	15.4 (24.9)	2.9 (25.7)	17.0 (26.5)	4.6 (21.0)	14.2 (25.3)	0.0 (17.1)	13 (22.8)	0.0 (18.2)
Sweet products and substitutes	0.0676	35.7 (37.8)	23.8 (41.1)	36.2 (40.5)	20.0 (42.0)	30.3 (35.8)	20.0 (35.6)	25.1 (27.3)	16.9 (31.0)
Water and other non-alcoholic beverages	<0.0001	1081.4^{a} (427.5)	1053.4 (0.5)	1755.2^{b} (681.3)	1651.3 (881.0)	1693.9^{b} (39.1)	1603 (832.4)	1495.5^{c} (506.6)	1430 (650.9)
Alcoholic beverages and substitutes	<0.0001	0.0^{a} (0.2)	0.0 (0.0)	9.1^{a} (87.9)	0.0 (0.0)	114.0^{b} (195.2)	0.1 (165.0)	113.9^{b} (171.0)	40.0 (165)
Meal substitutes	0.1487	0.0 (0.0)	0.0 (0.0)	0.0 (0.8)	0.0 (0.0)	0.3 (3.4)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Miscellaneous	0.0068	1.3^{a} (3.5)	0.0 (0.4)	3.9 (9.2)	0.0 (3.7)	2.6^{b} (5.8)	0.0 (3.0)	2.2 (4.9)	0.0 (2.5)

[a, b] Different superscript letters correspond to significantly different values ($p < 0.05$).
[a] Kruskal-Wallis test for differences in food groups' consumption across age classes.

consumption of powdered formula milk, while 14 % consumed liquid formula milk. Among infants under 6 months, regardless of whether they received breast milk or formula milk, *Fruit, fresh and processed* was the most consumed food group with an average amount of 29 g/day, followed by *Vegetables, fresh and processed*, *Meat, meat products and substitute* and *Cereals, cereal products and substitutes,* each with an average of less than 5 g/day. Overall, the consumption of all food groups, except milk, tend to increase with age. Fruit and cereals were the most consumed food groups in children aged 1–2 years, with an average of over 100 g/day (see supplementary material).

4. Discussion

The present work describes the IV SCAI study which provides the most recent data on food, beverage consumption and eating habits of the population in Italy. It is of great interest not only because offers data to evaluate the nutritional status of sample of Italian population ranging from age 3 months to 74 years, but also because it facilitates comparison with results from other European countries that have used the same methodology. The food consumption database described here is part of the EFSA Comprehensive database, according to the population group [46].

Our findings illustrate the mean of food consumption in terms of main food groups and subgroups by sex and age classes, of the entire sample and of consumers only.

More than 2 kg is the mean total amount of food and beverages consumed daily by the Italian population. This includes 1574 g/day of bottled and tap water (contributing 72 % to the total liquids consumed), coffee and tea, herbal tea, other non-alcoholic beverages and alcoholic beverages, milk, milk-based beverages and infant formula. The most consumed food groups are *Cereals, cereal products and substitutes* followed by *Fruit, fresh and processed*, *Vegetables, fresh and processed, Meat products and substitutes* and *Oils & Fats*. The last group is mainly used as seasonings and in the preparation of recipes. As well-known and such as numerous literature reviews demonstrate that a high intake of fruit and vegetables (F&V) has a potential health benefit for several diseases [47–50]. From the data analysis result that the mean daily intake of fruits and vegetable is 313 g/day varying with age. Infants (3–11 months) consume 137 g/day of fruit and vegetables, children (1–9 years) consume 208 g/day, and adolescents (10–17 years) consume 292 g/day.

These data deviate remarkably from the recently updated WHO recommendations [51], which suggest for preschool and school-age children a daily F&V intake of at least 250 g/day (2–5 years) and 350 g/day (6–9 years) respectively. For the other age groups the desirable level of intake is at least 400 g/day which is not met by adolescents, but on average by both adults with 407 g/day, and the elderly (65–74 years) with 552 g/day; females consume less of both fruit 189 g/day and vegetables 207 g/day than men who slightly exceed the recommended level with 199 g/day and 220 g/day of fruit and vegetables respectively. Similarly, elderly females consume 289 g/day of fruit and 240 g/day of vegetables lower amounts than elderly men (341 g/day and 243 g/day respectively). Moreover, at the total sample level, only 39 % of individuals have adequate F&V consumption. Adequacy for children and adolescents is less than 30 % but increases to 43 % and 73 % for adults and the elderly respectively. Comparing these consumption levels with the Italian dietary guidelines for healthy eating [18], the population under study appears to be below the objectives promoted to increase fruit and vegetable consumption among Italians. These objectives translate into at least 5 daily servings of fruit and vegetables, comprising two servings of vegetables (1 serving is approximately 200 g) and three servings of fruit (1 serving is approximately 150 g) [52].

At the European level, comparing data from similar surveys conducted since 2012 that joined the EFSA's EU Menu project [46], Italian adults and the elderly consume more F&V than those in other countries, while adolescents rank sixth in F&V intake, confirming their low intake.

Table 3
Mean intake, standard deviation (SD), median, interquartile range (IR) and high percentiles by food groups in total population and consumers (g/day).

Food groups	Total population (n = 1969)						Consumers							
	Mean	SD	Median	IR	P90	P95	n	%	Mean	SD	Median	IR	P90	P95
Cereals, cereal products and substitutes	*197.2*	*108.1*	*187.0*	*140.2*	*337.1*	*388.9*	*1950*	*99.0*	*199.6*	*106.4*	*189.2*	*139.6*	*337.2*	*389.3*
Bread	52.4	58.2	35.0	73.1	135.0	168.8	1493	75.8	69.6	57.2	50.0	75.0	147.2	178.4
Pasta & pasta substitutes	38.4	37.5	29.8	49.1	88.2	109.9	1555	79.0	48.8	35.7	40.0	41.9	95.4	118.9
Pizza	21.8	42.6	0.0	27.5	84.0	101.7	672	34.1	63.9	51.4	52.5	63.9	120.9	162.5
Rice	7.5	18.0	0.0	4.7	27.8	38.5	500	25.4	27.5	26.3	23.6	23.2	50.5	66.3
Wheat & wheat flours	5.2	12.1	0.0	5.3	16.2	26.6	753	38.2	14.0	16.2	8.6	12.6	30.5	48.0
Other cereals & flours	2.8	13.3	0.0	0.0	3.0	21.4	201	10.2	25.4	33.2	19.2	27.2	50.0	84.2
Breakfast cereals	3.2	9.6	0.0	0.0	13.5	21.0	285	14.5	20.8	15.7	17.0	20.0	40.0	50.0
Biscuits	18.4	23.8	9.0	30.0	51.0	65.0	1125	57.1	31.7	23.6	27.0	30.1	60.0	73.9
Savoury fine bakery products	14.8	25.3	2.5	19.6	43.5	63.2	966	49.1	29.2	29.4	19.5	25.5	62.8	86.0
Cakes and sweet snacks without creams	11.6	24.1	0.0	16.0	40.0	62.5	639	32.5	36.5	30.0	24.0	30.0	74.5	93.8
Cakes and sweet snacks with creams	16.6	32.2	0.0	24.5	53.5	79.5	733	37.2	46.8	37.9	35.0	34.5	93.8	120.0
Infant food_pasta	2.5	11.2	0.0	0.0	0.0	15	150	7.6	37.0	23.0	30.0	42.5	71.1	82.5
Infant food_biscuits	1.5	6.1	0.0	0.0	1.3	10.0	215	10.9	14.7	12.7	10.0	15.0	32.0	40.0
Infant food_other cereals	0.6	4.1	0.0	0.0	0.0	0.0	68	3.5	16.6	13.9	12.0	16.5	34.0	38.0
Pulses	*9.2*	*21.6*	*0.0*	*8.3*	*33.1*	*49.5*	*614*	*31.2*	*29.6*	*29.9*	*20.6*	*28.2*	*64.4*	*92.0*
Pulses, fresh and processed	6.6	19.1	0.0	0.0	22.1	40.0	412	20.9	30.7	31.4	20.9	28.4	70.0	95.5
Pulses, dried	2.3	8.5	0.0	0.0	6.2	15.8	263	13.4	18.6	16.1	13.0	17.7	41.8	50.4
Infant food_pulses	0.3	4.3	0.0	0.0	0.0	0.0	10	0.5	49.2	33.4	40.0	43.0	80.0	140.0
Vegetables, fresh and processed	*147.1*	*126.6*	*113.1*	*161.0*	*317.1*	*387.6*	*1926*	*98.0*	*150.2*	*126.0*	*115.9*	*160.2*	*317.2*	*389.8*
Leafy vegetables, fresh	26.3	46.4	2.5	32.8	83.2	121.4	1006	51.1	51.5	54.0	31.5	54.3	120.3	154.2
Tomatoes, fresh	33.0	51.7	14.1	46.9	96.8	132.2	1235	62.7	52.9	56.8	34.0	53.1	123.4	166.0
Other fruiting vegetables, fresh	0.4	3.8	0.0	0.0	0.0	0.0	25	1.3	23.7	21.7	17.5	25.0	48.8	50.0
Roots and onions, fresh	15.2	26.0	4.5	18.9	42.7	65.2	1669	84.8	17.8	27.4	7.2	21.1	47.0	70.2
Other vegetables, fresh	29.4	59.7	0.7	29.6	99.3	146.3	1032	52.4	55.1	73.3	26.5	66.8	142.0	202.9
Tomatoes, canned	13.9	22.6	0.0	20.6	42.3	60.1	960	48.8	29.5	24.5	22.0	28.7	60.8	78.6
Other vegetables, canned	0.6	4.3	0.0	0.0	0.0	0.0	86	4.4	13.3	15.7	8.8	10.3	35.0	42.7
Vegetables, dried	0.0	0.6	0.0	0.0	0.0	0.0	12	0.6	4.4	5.1	2.5	4.2	8.5	18.0
Spices and Herbs	2.0	3.1	1.0	2.8	5.5	8.0	1388	70.5	2.9	3.4	1.9	2.9	6.6	9.1
Other vegetables, packaged products	25.9	50.4	3.4	29.8	84.9	124.6	1159	58.9	43.3	59.5	20.0	53.8	112.2	159.0
Infant food_vegetables	0.2	3.5	0.0	0.0	0.0	0.0	12	0.6	39.3	23.6	40.0	0.0	47.5	117.5
Potatoes, tubers and their products	*33.7*	*54.1*	*4.7*	*50.3*	*109.0*	*151.6*	*1019*	*51.8*	*63.9*	*60.8*	*45.9*	*69.0*	*150.0*	*184.9*
Potatoes and potato products, excl. potato chips	31.6	53.5	0.0	46.7	104.5	150.0	918	46.6	66.4	61.5	50.4	69.2	150.5	191.3
Potato chips and french fries	2.0	8.7	0.0	0.0	0.0	15.0	183	9.3	21.7	19.8	17.5	20.0	40.0	70.0
Other tubers	0.0	0.4	0.0	0.0	0.0	0.0	1	0.1	22.0	0.0	22.0	0.0	22.0	22.0
Fruit, fresh and processed	*166.2*	*143.4*	*136.0*	*179.8*	*346.8*	*434.0*	*1763*	*89.5*	*184.4*	*139.9*	*152.4*	*171.8*	*358.0*	*445.0*
Citrus fruit, fresh	23.0	53.3	0.0	6.0	83.0	150.0	575	29.2	78.4	73.3	67.0	90.9	185.0	225.0
Berry fruit, fresh	4.2	18.9	0.0	0.0	0.0	28.6	152	7.7	48.3	47.4	36.0	46.5	108.3	131.5
Exotic fruit, fresh	21.9	40.9	0.0	37.0	75.0	110.0	634	32.2	68.3	45.2	54.0	48.4	127.5	150.0
Other fruit, fresh	104.1	129.6	67.8	155.0	275.0	342.5	1288	65.4	154.9	132.7	112.5	142.7	319.0	425.0
Nuts, dried fruit, seeds, olives and their products	4.7	11.6	0.0	3.3	16.0	25.0	640	32.5	13.8	16.8	8.8	14.9	32.0	41.3
Processed fruit (in syrup, in purée, etc.)	2.1	13.4	0.0	0.0	0.0	0.0	46	2.3	68.1	43.3	50.0	50.0	111.0	150.0
Infant food_fruit	6.3	26.4	0.0	0.0	0.0	50.0	150	7.6	88.4	48.7	87.5	50.0	150.0	200.0
Meat, meat products and substitutes	*99.8*	*88.6*	*81.0*	*106.0*	*215.2*	*271.0*	*1813*	*92.1*	*109.1*	*86.7*	*89.0*	*101.1*	*223.1*	*276.6*
Beef & veal, not preserved, excl. offal	30.5	53.9	0.0	47.5	97.2	130.0	935	47.5	64.9	62.5	51.8	69.8	136.5	191.8
Pork, not preserved, excl. offal	7.7	29.4	0.0	0.0	10.3	57.8	240	12.2	60.6	61.3	49.4	76.5	125.0	184.5
Poultry and game, not preserved, excl. offal	30.9	51.8	0.0	50.0	99.8	131.8	826	42.0	73.9	56.8	60.0	62.2	144.8	184.3
Other meats, not preserved, excl. offal	3.6	21.4	0.0	0.0	0.0	0.0	91	4.6	76.6	65.3	62.4	76.1	161.6	190.3
Ham, salami, sausages, excl. offal	22.6	31.7	10.4	35.0	64.8	81.8	1165	59.2	37.6	33.6	27.6	35.1	79.1	100.0
Other meats, preserved, excl. offal	0.2	2.2	0.0	0.0	0.0	0.0	23	1.2	15.6	13.2	13.0	16.5	32.0	45.0
Offal, and their products	0.8	9.8	0.0	0.0	0.0	0.0	27	1.4	64.9	60.4	32.0	75.9	126.2	229.0
Meat substitutes	0.2	3.7	0.0	0.0	0.0	0.0	10	0.5	41.6	28.6	35.0	20.6	90.0	90.0
Infant food_meat	3.4	16.6	0.0	0.0	0.0	20.0	129	6.6	60.9	34.2	40.0	40.0	120.0	140.0
Fish, seafood and their products	*33.3*	*55.7*	*0.0*	*50.0*	*108.8*	*150.0*	*975*	*49.5*	*68.1*	*62.6*	*50.0*	*77.8*	*150.4*	*195.4*

(*continued on next page*)

Table 3 (*continued*)

Food groups	Total population (n = 1969)						Consumers							
	Mean	SD	Median	IR	P90	P95	n	%	Mean	SD	Median	IR	P90	P95
Fish, fresh and frozen	20.9	44.5	0.0	15.9	84	113.7	545	27.7	78.8	52.7	68.6	65.3	146.6	192.5
Seafood, fresh and frozen	6.3	27.2	0.0	0.0	6.0	41.2	207	10.5	58.7	62.6	36.0	66.5	138.4	172.2
Fish and seafood, preserved	5.5	17.1	0.0	0.0	20.0	39.0	396	20.1	26.5	29.6	19.3	29.8	57.5	71.7
Infant food_fish	0.6	5	0.0	0.0	0.0	0.0	40	2.0	35.8	12.6	40.0	20.0	40.0	60.0
Milk, milk products and substitutes	*237.0*	*197.4*	*202.4*	*208.6*	*455.5*	*591.7*	*1925*	*97.8*	*241.9*	*196.6*	*206.1*	*203.8*	*459.1*	*595.0*
Milk and milk-based beverages	115.4	134.3	80.0	200.0	275.4	375.6	1272	64.6	178.1	129.3	167.8	160.0	330.0	419.3
Milk substitutes plant-based	3.9	17.3	0.0	0.0	0.0	30.0	128	6.5	54.5	40.0	50.0	37.5	100.0	125.0
Yoghurt and fermented milk	25.2	46.3	0.0	57.5	85.0	125.0	565	28.7	84.1	48.1	62.5	50.0	135.0	150.0
Cheese and substitutes	37.0	37.8	26.0	44.4	88.6	113.7	1752	89.0	41.5	37.7	30.9	45.5	91.8	116.5
Milk-based desserts and substitutes	7.3	42.9	0.0	0.0	0.0	0.0	79	4.0	169.3	128.1	135.0	150.0	345.0	422.5
Human milk	31.7	157.8	0.0	0.0	0.0	125.0	108	5.5	548.7	395.5	485.3	550.0	1208.0	1317.5
Infant formula, liquid	10.2	66.3	0.0	0.0	0.0	0.0	68	3.5	347.8	167.3	357.5	225.0	585.0	640.0
Infant formula, powder	2.3	13.0	0.0	0.0	0.0	0.0	86	4.4	50.3	35.9	41.3	35.0	90.5	130.1
Infant food_yoghurt	3.3	17.4	0.0	0.0	0.0	0.0	105	5.3	73.8	37.0	62.5	50.0	125.0	125.0
Infant food_cheese	0.7	4.3	0.0	0.0	0.0	0.0	84	4.3	18.6	12.5	10.4	10.4	40.0	40.0
Oils & Fats	*24.7*	*16.1*	*22.0*	*19.4*	*46.3*	*56.1*	*1939*	*98.5*	*25.2*	*15.8*	*22.4*	*19.2*	*46.8*	*56.1*
Olive oil	20.8	13.9	18.2	18.4	38.4	47.9	1927	97.9	21.3	13.6	18.6	17.8	38.8	48.2
Other vegetable oils	1.3	3.5	0.0	0.4	5.3	9.1	523	26.6	5.1	5.3	3.5	5.8	10.4	13.5
Butter & creams	2.0	6.7	0.0	0.0	6.3	12.0	403	20.5	8.7	12.5	5.8	7.4	18.0	24.4
Margarine	0.0	0.2	0.0	0.0	0.0	0.0	3	0.2	3.5	3.5	1.1	4.9	6.0	6.0
Mayonnaise and fat-based sauces	0.5	3.0	0.0	0.0	0.0	3.0	147	7.5	7.3	8.4	6.0	6.5	12.0	17.6
Other animal fats	0.1	0.8	0.0	0.0	0.0	0.0	13	0.7	8.0	5.1	7.5	10.0	13.6	19.1
Eggs	*13.2*	*23.4*	*0.0*	*16.8*	*46.9*	*64.1*	*935*	*47.5*	*28.6*	*27.0*	*20.1*	*32.0*	*65.5*	*83.8*
Sweet products and substitutes	*26.5*	*34.4*	*15.0*	*35.4*	*69.5*	*95.5*	*1519*	*77.1*	*34.1*	*35.7*	*22.6*	*36.0*	*79.1*	*101.1*
Ice cream, ice lolly and substitutes	13.1	29.1	0.0	0.0	49.5	80.0	469	23.8	53.4	36.7	40.0	45.0	100.0	122.5
Chocolate and substitutes	3.8	8.6	0.0	3.4	12.6	20.0	576	29.3	13.4	11.4	10.0	13.0	30.0	35.0
Candies, jam and other sweet products (incl. sugar-free)	4.1	9.8	0.0	2.7	13.8	25.0	606	30.8	12.8	14.1	9.5	14.4	30.0	40.0
Sugar, fructose, honey	5.1	8.8	0.0	8.0	16.0	22.5	863	43.8	11.4	10.2	8.0	11.8	23.8	30.3
Cocoa and cocoa based powder	0.5	2.2	0.0	0.0	0.0	3.8	187	9.5	5.3	4.9	4.5	5.4	9.8	13.5
Artificial sweeteners	0.0	0.1	0.0	0.0	0.0	0.0	39	2.0	0.5	0.6	0.3	0.7	1.3	2.3
Water and other non-alcoholic beverages	*1327.8*	*711.2*	*1244.3*	*917.5*	*2253.4*	*2600.6*	*1960*	*99.5*	*1335.4*	*705.4*	*1250.0*	*914.9*	*2255.0*	*2600.6*
Tap water (as such, in beverages or recipes)	480.4	599.4	240.0	770.0	1359.2	1740.0	1438	73.0	643.5	620.1	440.0	819.7	1516.3	1871.8
Bottled water	655.5	639.1	500,0	916.0	1545.0	1920.0	1558	79.1	836.6	604.9	720.0	790.0	1687.5	2000.0
Herbal tea	17.9	64.5	0.0	0.0	75.0	110.0	206	10.5	154.8	128.2	110.0	100.0	280.0	420.0
Coffee, tea, and substitutes (incl. decaffeinated)	95.9	137.4	37.5	150.0	258.8	340.0	1034	52.5	179.4	143.9	150.0	133.0	335.6	440.0
Fruit & vegetable juices without artificial sweeteners	41.9	75.2	0.0	80.0	150.0	201.2	850	43.2	98.7	87.0	100.0	128.0	210.0	246.0
Non-alcoholic beverages without artificial sweeteners	29.1	91.9	0.0	0.0	120.0	200.0	313	15.9	187.6	155.6	160.0	160.0	363.8	495.0
Non-alcoholic beverages with artificial sweeteners	6.7	46.9	0.0	0.0	0.0	0.0	74	3.8	183.6	165.0	135.0	160.0	330.0	500.0
Non-alcoholic beverages, powder	0.2	1.4	0.0	0.0	0.0	0.1	90	4.6	4.7	4.6	3.5	2.5	10.0	13.5
Infant food_fruit juices and beverages (incl. powders)	0.3	4.5	0.0	0.0	0.0	0.0	23	1.2	25.3	35.2	9.0	22.0	80.0	100.0
Alcoholic beverages and substitutes	*52.1*	*143.2*	*0.0*	*0.1*	*190.0*	*325.0*	*683*	*34.7*	*146.5*	*212.0*	*80.0*	*214.9*	*400.1*	*531.3*
Regular wine and substitutes	28.6	88.8	0.0	0.1	95.2	200.0	591	30.0	92.0	142.3	40.0	158.4	240.2	360.0
Beer, cider and substitutes	20.6	87.8	0.0	0.0	0.0	165.0	179	9.1	234.3	191.1	165.0	155.0	425.0	712.5
Sweet wine, spumante, aperitif	2.1	19.7	0.0	0.0	0.0	0.0	34	1.7	131.5	85.0	113.0	76.0	240.0	390.0
Spirits & liquors	0.9	5.7	0.0	0.0	0.0	0.0	78	4.0	20.6	19.5	20.6	20.6	55.0	55.0
Meal substitutes	*0.1*	*2.1*	*0.0*	*0.0*	*0.0*	*0.0*	*8*	*0.4*	*26.4*	*18.0*	*20.0*	*7.5*	*56.0*	*56.0*
Miscellaneous	*2.1*	*5.6*	*0.0*	*1.3*	*6.0*	*12.0*	*653*	*33.2*	*5.7*	*8.4*	*3.0*	*6.1*	*14.0*	*21.2*
Non-fat-based sauces and condiments	1.9	5.5	0.0	0.0	6.0	11.5	445	22.6	7.8	9.1	5.0	7.5	18.0	25.0
Broth cubes and other products	0.2	0.7	0.0	0.0	0.4	1.3	271	13.8	1.2	1.5	0.5	1.3	3.3	3.9
Flavors	0.0	0.0	0.0	0.0	0.0	0.0	1	0.1	0.1	0.0	0.1	0.0	0.1	0.1
Total amount of food and beverages	2370.9	938.8	2292.0	1353.3	3621.8	4005.5	1965	99.8	2374.7	936.9	2294.7	1340.7	3623.7	4005.5
Total Liquid	1547.4	704.3	1433.5	920.0	2471.3	2905.1	1969	100.0	1547.4	704.3	1433.5	920	2471.3	2905.1
Total Solid	823.6	360.6	787.5	490.3	1283.7	1442.1	1965	99.8	825.6	358.7	788.1	491.5	1286	1442.1

The consumption of red and processed meat is being monitored by national and international institutions since their excessive intake is associated with increased risk of NCDs and unsustainable environmental impacts, such as greenhouse gas (GHG) emissions, freshwater use, land mass and biodiversity loss [53]. The WHO suggested red meat intake should be between 98 g and 500 g per week for adults, about 70 g/day. The mean consumption of the sampled adults is 83.2 g/day slightly above the recommended level, while adolescents exceed this level by about 29 %, reaching a mean intake of 100.4 g/day.

It should be noted that to facilitate comparison between surveys, the food categorization presented here is different from that recommended by EFSA, the Foodex2 classification system, and it is closer to that adopted in the previous INRAN SCAI 2005–2006 survey.

This is done both to facilitate comparison between the results of the two surveys and to give a more nutritional approach than exposure assessment, which is one of the priorities of EFSA's activities. In any case, it is important to highlight that the number of subgroups, in the survey described here, increased from 57 in the past to 93. This extension aims to include baby foods and to better highlight the consumption of some substances of interest, such as artificial sweeteners in *Water and other non-alcoholic beverages*.

Given these premises, a comparison of the two surveys on the total sample shows that the mean intakes at the food group level are all lower except for milk (198 g/day INRAN SCAI 2005-06 vs 237 g/day), because of to the larger sample of children in the IV SCAI, and for drinking water, (649 g/day INRAN SCAI 2005–06, 1136 g/day IV SCAI), since interviewers were particularly sensitized to report information about water consumed during the day. At the age group levels, for adults and adolescents, the intake of fruit and vegetables decreases, when comparing INRAN-SCAI and IV SCAI respectively (161.3 g/day Fruit and 175.1 g/day Vegetables vs 146.4 g/day Fruit and 145.1 g/day Vegetables for adolescents; 208.9 g/day Fruit and 222.1 g/day Vegetables vs 193.6 g/day Fruit and 213.1 g/day Vegetables for adults), while the intake of meat products increases (123.8 g/day vs 143.1, for adolescents and 113.1 g/day vs 124.2 g/day for adults).

The difference in intakes is partly attributed to the different methodologies adopted in the two national surveys: as mentioned before, INRAN SCAI was conducted at the household level and considered consumption on three consecutive days reported by food diaries; on the other hand, IV SCAI is carried out at the individual level and takes into account two non-consecutive days, resulting in greater variability in the assessment of average consumption. In addition, food diaries were used only for children up to 9 years of age, and the 24-h recall for older subjects. Another methodological change to consider when comparing consumption in grams, is the increase in the number of servings for each food and recipe to six, compared to the three servings used in the previous INRAN-SCAI study. A strength of this study, as well as the previous one, is the reference study for monitoring the diet of the Italian population and helps identify dietary trends, assess nutritional deficiencies or excesses, monitor changes in eating habits, and evaluates the effectiveness of interventions and nutrition programs. Therefore, it is essential for the development of the Italian Dietary Guidelines for Healthy Eating [18,19], that are going to be revised in 2024, and the Reference Intake Levels of Nutrients and Energy for the Italian population (LARN) [20] already updated considering the consumption and intake assessments from the latest national survey. In addition, another positive aspect is that the study is based on the sampling of individuals rather than families, and a greater representation of children than in the past has been achieved, particularly of infants and adolescents,

Moreover, the involvement of highly specialized and motivated fieldworkers, distributed throughout the whole Italian country who selected subjects from local lists of people likely trusting the interviewers, aimed to achieve a higher response rate. Even so, the response rate for the children's survey was 44 %. Regarding the reasons for refusal among the sample of individuals who accepted to fill out the non-respondent questionnaire, the main reason was "lack of time" (68 %), the second was "lack of interest" (17 %), followed by "parent's health" (7 %).

For the adult survey, the response rate was 84 % and 6 % of the contacted subjects refused to participate, out of which the 2.6 % during the second recall. Another 8 % were not included in the survey due to incorrect age class, missed contact, or having other relatives already recruited. Finally, 2 % of subjects were excluded due to lack of reliability of the reported information. Among the subjects who refused to participate and filled in the refusal questionnaire, the most frequent reply was "lack of time" (32 %), followed by "lack of interest" (6 %), while 51 % did not give any answer. In the previous Italian national food consumption survey [5], the participation rate was 33 %.

Among the different causes that affected the participation rate was the COVID health emergency. Due to travel bans, lockdowns, and social distancing measures implemented throughout the national territory, the research team was forced to stop data collection from March to April 2020 to ensure the safety of the personnel involved as well as the participants and to comply with imposed legal conditions or requirements/restrictions. After the above-mentioned two months, data collection was carried out remotely through web applications (where and when possible) and/or by phone. The switch from 'in person' to 'remote' mode made it possible to continue the study's activities; on the other hand, the protocol amendments led to major problems to the recruitment of participants and the activities conducted by the interviewers (e.g., delays due to many contracting COVID-19). Furthermore, this problem entailed the impossibility of reaching the sample size suggested by EFSA for the infants and elderly age groups. Finally, another limitation includes the failure to monitor the number of anthropometric measurements at home or in the doctor's office/clinic.

5. Conclusion

The data collected through the IV SCAI survey are the key reference for Italian food consumption and are useful for a variety of purposes, including assessment of nutrient intake, evaluation of dietary adequacy, potential updating nutritional recommendations and dietary guidelines, as well as risk analysis. Furthermore, these data are needed to carry out various research and surveillance activities in the fields of consumer science, nutrition and food safety, and are also used to assess the environmental impact of diet. Updating information on food consumption and nutrient intakes is essential for monitoring the population's dietary patterns and obtaining insights for implementing nutrition education interventions, developing nutritional policies, and, finally, to provide data for the assessment of the sustainability of the agri-food system. The present study will be used as a prototype experience to promote a model of a continuous surveillance system to conduct nationwide studies on diet assessment on a regular basis.

Author contributions

All authors contributed to the conception, design and implementation of the national survey; LM performed the statistical analyses and drafted the manuscript; CLD drafted the manuscript; GC, FJC, LD, MF, DM, RP, SS, AT contributed to critical revisions of the manuscript. All authors have read and agreed to the published version of the manuscript.

Disclaimers

All authors declare no conflicts of interest.

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Declaration of competing interest

The authors have nothing to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.numecd.2025.103863.

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Original article

Development and validation of a computerized web-based quantitative food frequency questionnaire

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SUMMARY

Background & aims: Epidemiological research is progressing towards digital data collection. This study aimed to evaluate the validity and reproducibility of our new computerized, and easy-to-use Food Frequency Questionnaire (FFQ).

Methods: Participants' dietary intake was assessed using 24-h Dietary Recalls (DRs) and our FFQ, consisting of 133 food items and beverages. The software allows users to choose between three visualized portion sizes, categorizes the selections into food groups with three degrees of food processing levels, and produces a visualized output of the results. The reproducibility of the FFQ was evaluated based on two user submissions, and its validity was measured by comparing its calculated caloric intake and macro and micro-nutrient consumption to the equivalent mean values from three 24-h DRs. Thirty-nine women of fertility age [18–45] were recruited to the study, of whom twenty-six qualified for reproducibility testing and thirty-one qualified for validity testing.

Results: For most nutrient intakes, the FFQs yielded higher scores than the 24-h DRs, resulting in a less satisfactory agreement between them due to FFQs overestimation. The Intra Class Correlation (ICC) coefficient between the two FFQs ranged from moderate for calcium (0.55) to high for magnesium (0.83) ($p < 0.05$), indicating good reproducibility. Evaluation of food groups and processed food reproducibility scores yielded ICC coefficients ranging from moderate (0.53; super-processed foods) to high (0.83; non-processed foods) ($p < 0.05$). Spearman's correlation coefficient showed a moderate (sugar-sweetened beverages) to strong (non-processed foods) correlation ($p < 0.05$).

Conclusions: The FFQ we developed and validated in this study showed moderate to high reproducibility and acceptable validity in a group of thirty-nine women of fertility age. Moreover, it is highly adjustable and easy to use, and its digital-based delivery enables large-scale, multilingual nutritional research.

1. Introduction

Given the influence that food can have on the development, prevention, and treatment of diseases, having a thorough knowledge of the population's dietary habits is of vital importance [1]. Two main methods are used to assess diet in research, 24-h Diary Recall (24-h DR) and Food Frequency Questionnaires (FFQ); both provide reasonably precise variability estimates between individuals and groups [2]. Collecting nutritional epidemiology data

Abbreviations: FFQ, Food Frequency Questionnaire; ICC, Intraclass Correlation Coefficient; DR, Dietary Recalls.

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Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2 FFQ1	3	4	5	6	7	8
9	10	11 DR1	12 DR2	13	14	15 DR3
16 FFQ2	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

Fig. 1. Computerized FFQ study design.

comes with significant methodological challenges. Besides relying on individuals' memory, FFQs are primarily delivered using paper forms, with or without interviews [3]. In a recent systematic review, only three FFQs were sent to participants as electronic questionnaires despite the fact that the world is progressing towards new technologies [4]. Another essential parameter monitored in FFQs is portion size, which typically appears as a single-size verbal description, even though multiple portion sizes and visualization, such as pictures or food model samples, are preferred. Only one of sixty reported studies presented portion size visually, using multiple and diverse pictures [4]. This discrepancy may be linked to food intake overestimation in FFQs compared to other nutritional assessment methods [4–6]. Overestimation in FFQs is especially high when the questionnaires are filled by women, although this can be offset using statistical methods [7]. Furthermore, most FFQs do not collect information such as individual nutrition quality and food processing level [8–11]. The above-described issues are also present in Israeli studies [12,13]. However, while most FFQs do not distinguish between gender or age, distinction in nutritional data gathered from different age groups in Israel was performed [14–17]. To the best of our knowledge, large-scale data collection of dietary habits during pregnancy has not been performed in Israel [18,19]. This research is part of a large study assessing women's diet before pregnancy and the association between their diet, lifestyle, and development of pre-eclampsia (PE) [20]. Various studies [21–23] have shown that the FFQ is a useful and reproducible tool for examining and finding relations between preconception nutrition and the development of pregnancy complications—such as gestational hypertension and gestational diabetes mellitus [24] and birth outcomes such as birth weight [25]. Here, we present our

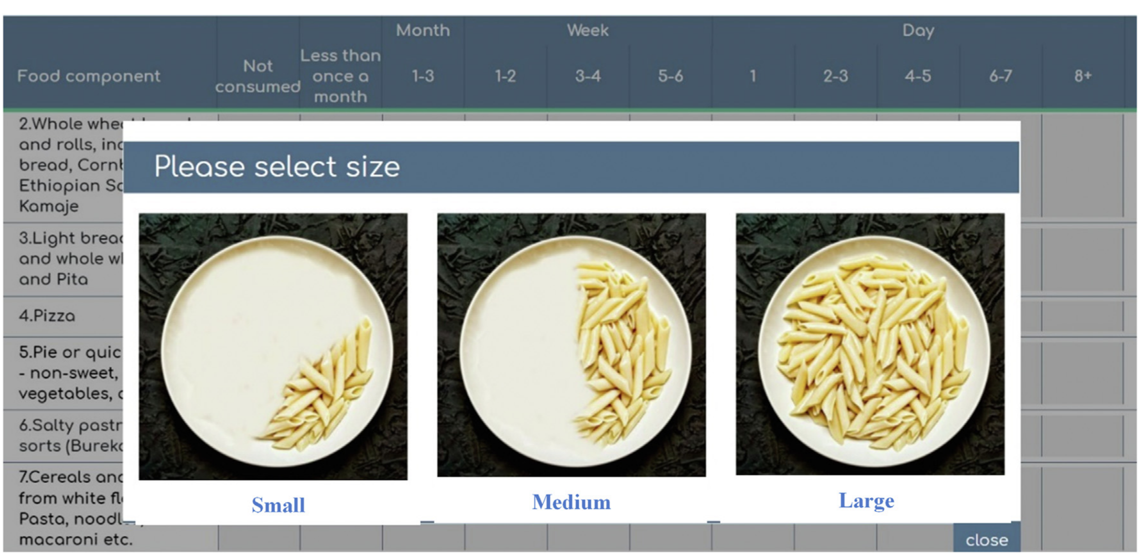

Fig. 2. Visualization of three different portion sizes of pasta.

newly developed computerized and automated FFQ, consisting of 133 food items and beverages used to assess dietary intake during the three crucial months preconception. An FFQ was used for a short-term study despite the fact that FFQs are usually used to gather long-term (one year) data [26] to minimize overreporting of dietary intake, as reported in several other studies [27–29]. Since the study focused on women before pregnancy, calcium-rich food items were added due to their possible role in PE prevention [30]. In addition, an improved portion size presentation was implemented using pictures of food divided into three sizes: small, medium, and large. Further advantages of the computerized FFQ are categorization to food groups and levels of food processing, automatic intake calculations of 74 nutrients, and ease of adjustment to other populations such as men, seniors, children, etc.

2. Materials and methods

2.1. Study design

This cross-sectional study aimed to validate and assess the reproducibility of a computerized FFQ on a sample of women within fertility age before implementing it on a large-scale group to evaluate women's diet before pregnancy. The large-scale study will explore possible associations between diet, lifestyle, and PE.

Participants completed the FFQ twice, two weeks apart, and were asked to refer to their nutritional consumption habits during the last three months. In addition, participants were asked to report three days of 24-h DR—two weekdays and one weekend day—during the two-week interval between FFQs (Fig. 1). Participants reported the three days via a web food diary we created following specific instructions sent by e-mail. The latest publications show a good to strong agreement between web-based 24-h DRs and respective reference measures for intakes of macro and micronutrients [31].

2.2. Study population

A total of 39 women volunteers, ages 18–45, were recruited for the study. The participants were employees, students, and visitors of the Technion – Institute of Technology, Haifa, Israel. The only exclusion criterion was suffering from chronic disease that affects diet, such as diabetes, irritable bowel syndrome, inflammatory

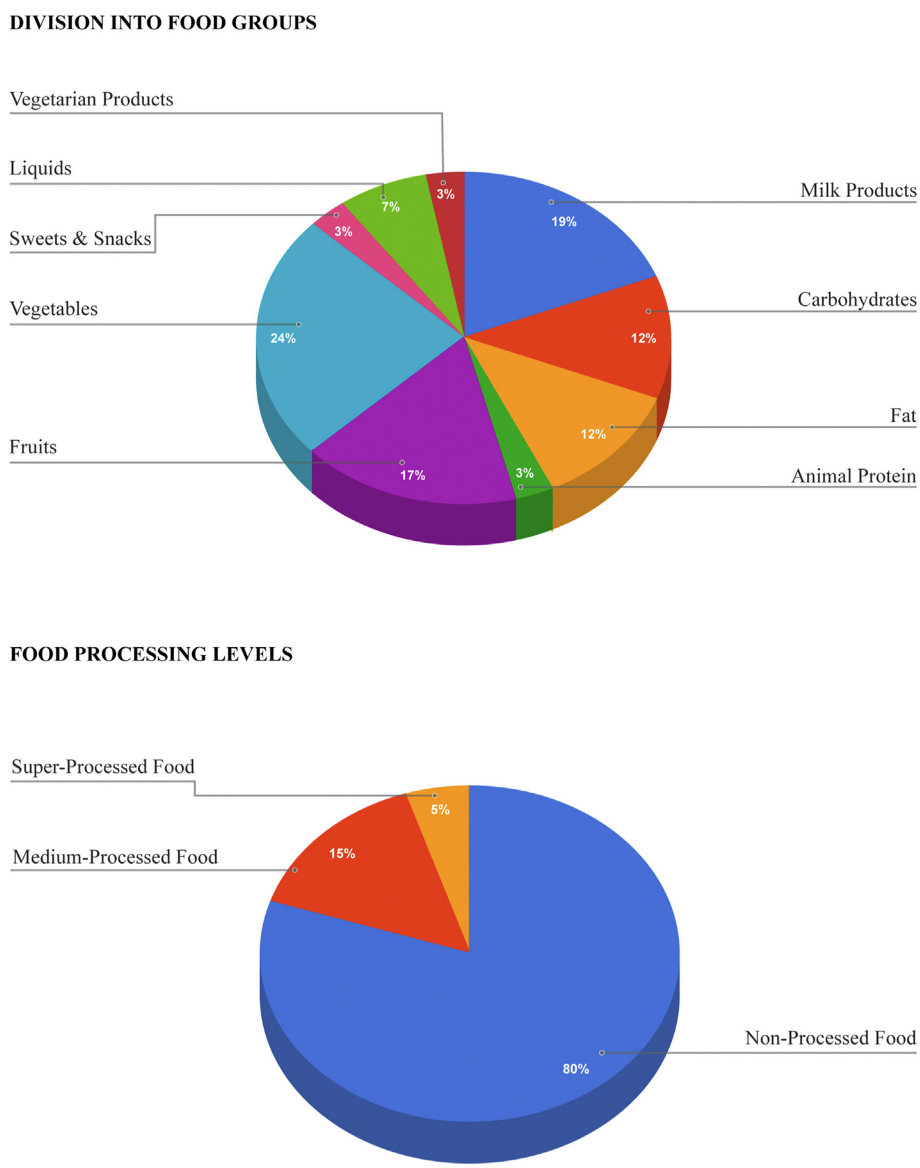

Fig. 3. Nutrition quality output.

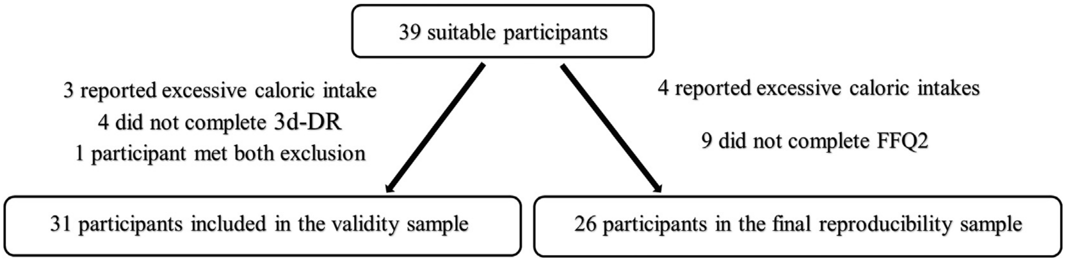

Fig. 4. Sample sizes included in each part of the study.

bowel disease, and end-stage kidney disease. The study protocol was approved by the board of ethics of the Rambam Medical Center, Haifa, Israel (registration number 0310-15-RMB) and conducted from January to September 2019. All subjects gave their electronic consent before inclusion in the study.

2.3. Methodology

Following a positive response to recruitment ads, a computerized FFQ link with video instructions was sent to participants. Besides the FFQ, sociodemographic and personal information data was collected. Reproducibility of the study was assessed by comparing FFQ1 to FFQ2 intake, filled out at a two-week interval, and validity was assessed by comparing the intake from FFQ1 to the mean of three 24 h-DR (Mean 3d-DR), which included one weekend day, as described in previous studies [28,32,33].

The automated, computerized FFQ was developed to resemble the one used by the Israeli Ministry of Health [34] to enable related reference to former local nutritional epidemiological data. Nevertheless, some modifications and improvements were necessary, such as updating the database according to new regulations in the food industry and adding new food items available on the market. Missing data was adapted from the United States Department of Agriculture (USDA) database. The questionnaire contains 133 food items, 20 of which are new—including a variety of protein-enriched products, dairy products, and caffeine drinks—with the following frequency response categories: “not consumed”, “less than once a month”, “1–3 times a month”, “1–2, 3–4, and 5–6 times a week”, “1,2–3, 4–5, 6–7, and over 8 times a day”.

Our software allows the user to choose between three visualized portion sizes (Fig. 2), which were weighed before photographing. In addition, the tool calculates division into food groups (milk products, carbohydrates, fat, animal protein, fruits, vegetables, sweets & snacks, sugar-sweetened beverage, alcohol, liquids, and vegetarian products). Furthermore, three degrees of food processing levels are reported, resembling the NOVA classification [35]: non-processed food items, medium-processed food items, and super-processed food items. An automated calculation of 74 micro and macronutrients is provided for each food item, and an output of these parameters, indicating the quality of an individual's nutrition (henceforth “nutrition quality”), is presented visually immediately after filling out the FFQ (Fig. 3). Since the computerized system is very flexible, future adaptation to changes in nutrient content and food products is simple and easy, in addition to the possibility of translation into multiple languages.

2.4. Data calculation

Nutritional information was collected through the calculations performed by the computerized FFQ. Intake frequencies were converted into factors representing daily intake by multiplying the selected portion size with each food item's 74 micro and macronutrient components, as stored in the nutrient database. Calculation of the Mean 3d-DR intake was performed using the same database. We chose to focus on 12 micro and macro-nutrients: energy, protein, fat, carbohydrates, fibers, calcium, iron, folate, sodium, magnesium, vitamin B12, and cholesterol. Additionally, the computerized FFQ provided a consumption of rate percentage for each category level of food processing. All three categories were evaluated: non-processed food items, medium-processed food items, and ultra-processed food items. The program also calculates and reports consumption frequencies of food groups, enabling the use of tools and scales for food quality, such as the healthy eating index (HEI-2015) to be implemented [36].

2.5. Statistical analysis

The data for this study was analyzed using the IBM SPSS version 23 and R statistical software version 3.5.0. Missing or incomplete DRs and FFQs, and participants with caloric intakes under 600 kcal or over 4000 kcal per day, were excluded from the study [6]. Of the 39 participants recruited to the study, 3 reported a caloric intake of over 4000 kcal per day, and 4 failed to complete full 3 days of 24-h DR. Therefore, the 4 who failed to complete the full 3 days of 24-h DR were excluded from validity testing but still used to test reproducibility. In addition, 9 out of 39 failed to complete FFQ2, and were therefore excluded from reproducibility but still used to test validity. A single participant reported excessive caloric intake and failed to complete the 3 full days of 24-h DR, so she was excluded

Table 1
Sociodemographic and anthropometric characteristics of the study population (n = 35).

Characteristic (units)	Value (n = 35)
Age (years), Mean (SD)	30.6 (6.29)
BMI (kg/m^2), Mean (SD)	23.1 (3.8)
BMI index level, n (%)	
Normal weight	28 (77.8%)
Overweight	7 (19.4%)
Obese	1 (2.8%)
Income per month, n (%)	
Lower than average salary[a]	17 (47.2%)
Higher than average salary[a]	19 (52.8%)
Employment, n (%)	
Full-time	12 (33.3%)
Part-time 50%	7 (19.4%)
Part-time 25%	3 (8.3%)
Other	14 (38.9%)
Living area, n (%)	
Urban	27 (75%)
Rural	9 (25%)
Marital status, n (%)	
Married	14 (39.9%)
Single	12 (33.3%)
In a relationship	10 (27.8%)

[a] 6700 NIS is the average salary in Israel.

Table 2
FFQ Reproducibility. A comparison between FFQ1 and FFQ2, Spearman's correlation coefficient (rs), and ICC (Mean ± SD, n = 26).

Nutrients	FFQ1	FFQ2	Spearman Correlation (rs)[c]	ICC[d]
	Mean ± SD	Mean ± SD		
Energy (kcal)	2007.64 ± 689.77	2097.88 ± 683.1	0.61[b]	0.74[b]
Carbohydrate (g)	222.99 ± 92.52	218.19 ± 76.94	0.67[b]	0.77[b]
Protein (g)	84.45 ± 28.68	92.59 ± 32.54	0.55[b]	0.70[b]
Fat (g)	77.78 ± 31.72	85.58 ± 31.8	0.53[b]	0.70[b]
Fibers (g)	44.05 ± 25.49	43.03 ± 19.95	0.64[b]	0.80[b]
Calcium (mg)	1084.25 ± 428.54	1171.54 ± 439.30	0.47[a]	0.55[a]
Iron (mg)	13.89 ± 6.07	14.42 ± 5.06	0.63[b]	0.74[b]
Folate (mg)	482.74 ± 227.57	517.40 ± 219.10	0.67[b]	0.82[b]
Vitamin b12 (μg)	4.00 ± 2.32	5.07 ± 2.99	0.79[b]	0.78[b]
Sodium (mg)	3463.28 ± 1150.15	3640.74 ± 1182.31	0.59[b]	0.73[b]
Magnesium (mg)	494.69 ± 208.37	504.67 ± 182.13	0.62[b]	0.83[b]
Cholesterol (mg)	261.89 ± 123.44	352.15 ± 186.78	0.65[b]	0.70[b]

[a] Spearman's correlation or ICC, $p < 0.05$.
[b] Spearman's correlation or ICC, $p < 0.01$.
[c] Spearman's correlation coefficient values: (0.3>)—weak, (0.40–0.70)—moderate, (>0.70)—strong.
[d] ICC values: (<0.5) -poor reliability, (0.5–0.75)—moderate reliability, (0.75–0.9)—good reliability, (>0.90)—excellent reliability.

entirely from the study. Fig. 4 presents the final sample size included in every study stage.

2.6. Reproducibility of the food frequency questionnaire

Intraclass Correlation Coefficients (ICCs) were calculated to assess the reliability between FFQ1 and FFQ2. ICC classification is as follows: Poor reliability (<0.5), moderate reliability (0.5–0.75), good reliability (0.75–0.90), and excellent reliability (>0.9) [37]. Spearman's correlation coefficient was used to assess the relationship between FFQ1 and FFQ2. Spearman's correlation ranges from weak (<0.3), through moderate (0.4–0.7), to strong correlation (>0.7) [38]. The final sample for the reproducibility consisted of 26 out of 39 subjects since 9 did not complete FFQ2 and 4 of the participants likely overestimated their intake (reported over 4000 Kcal/day), as previously mentioned [4–7].

2.7. Validity assessment of the food frequency questionnaire

For the validity assessment of the FFQ, caloric intake and micro and macro-nutrient intake as derived from the FFQ were compared with Mean 3d-DR. We used Bland–Altman plots to graphically examine the agreement between the FFQ and Mean 3d-DR [39]. The x-axis represents the average nutrient intake measured by the FFQ and the Mean 3d-DR, and the y-axis represents the differences in intake between the FFQ and the Mean 3d-DR.

3. Results

3.1. Pre-FFQ data

Sociodemographic and personal information of the participants in the study is presented in Table 1. As for anthropometric data, most of the participants (77.8%) reported a normal Body Mass Index (BMI), according to WHO criteria [40].

3.2. Reproducibility of the food-frequency questionnaire

Mean energy intake and macro and micro-nutrient consumption, as obtained from both FFQs (filled two weeks apart), are presented in Table 2. ICC between the two FFQ measurements ranged from moderate, 0.55 (for calcium), to high, 0.83 (for magnesium) ($p \leq 0.05$). Spearman's correlation presented mostly moderate correlation, rs = 0.47 (calcium) to rs = 0.67 (carbohydrates & folate). None of the nutrients showed weak correlation (<0.3), and one nutrient had strong correlation, rs = 0.79 (vitamin B12) ($p < 0.05$).

Table 3
Food groups and processed food reproducibility. comparison between FFQ1 and FFQ2, Spearman's correlation (rs), and the ICC (Mean ± SD, n = 26).

Item score	FFQ 1	FFQ 2	Spearman Correlation (rs)[A]	ICC[β]
	Mean ± SD	Mean ± SD		
Non-processed food	48.70 ± 7.56	47.24 ± 7.53	0.79[b]	0.91[b]
Medium processed food	25.15 ± 9.82	24.52 ± 8.43	0.75[b]	0.77[b]
Super processed food	6.15 ± 6.55	5.25 ± 2.94	0.72[b]	0.53[a]
Dairy products	8.92 ± 4.15	8.62 ± 3.88	0.59[b]	0.63[b]
Carbohydrates	8.96 ± 2.16	8.96 ± 2.35	0.69[b]	0.83[b]
Fat	8.56 ± 2.56	8.96 ± 2.77	0.73[b]	0.84[b]
Animal protein	8.63 ± 2.32	8.45 ± 2.53	0.69[b]	0.86[b]
Fruits	11.07 ± 2.66	10.92 ± 2.55	0.71[b]	0.88[b]
Vegetables	14.41 ± 2.32	13.84 ± 2.61	0.71[b]	0.73[b]
Sweets & Snacks	8.63 ± 3.57	8.96 ± 3.62	0.77[b]	0.90[b]
Sugar-sweetened beverage	1.68 ± 0.67	1.89 ± 0.83	0.58[a]	0.74[b]
Alcohol	2.13 ± 0.87	2.26 ± 0.73	0.76[b]	0.90[b]
Liquids	3.63 ± 1.00	3.44 ± 1.00	0.78[b]	0.85[b]
Vegetarian products	1.84 ± 1.03	1.91 ± 0.97	0.63[b]	0.57[a]

[A]Spearman's correlation coefficient values: (0.3>)—weak (0.40–0.70)—moderate (>0.70)—strong.
[β]ICC values: (<0.5)—poor reliability (0.5–0.75)—moderate reliability (0.75–0.9)—good reliability (>0.90)—excellent reliability.
[a] Spearman's correlation or ICC, $p < 0.05$.
[b] Spearman's correlation or ICC, $p < 0.01$.

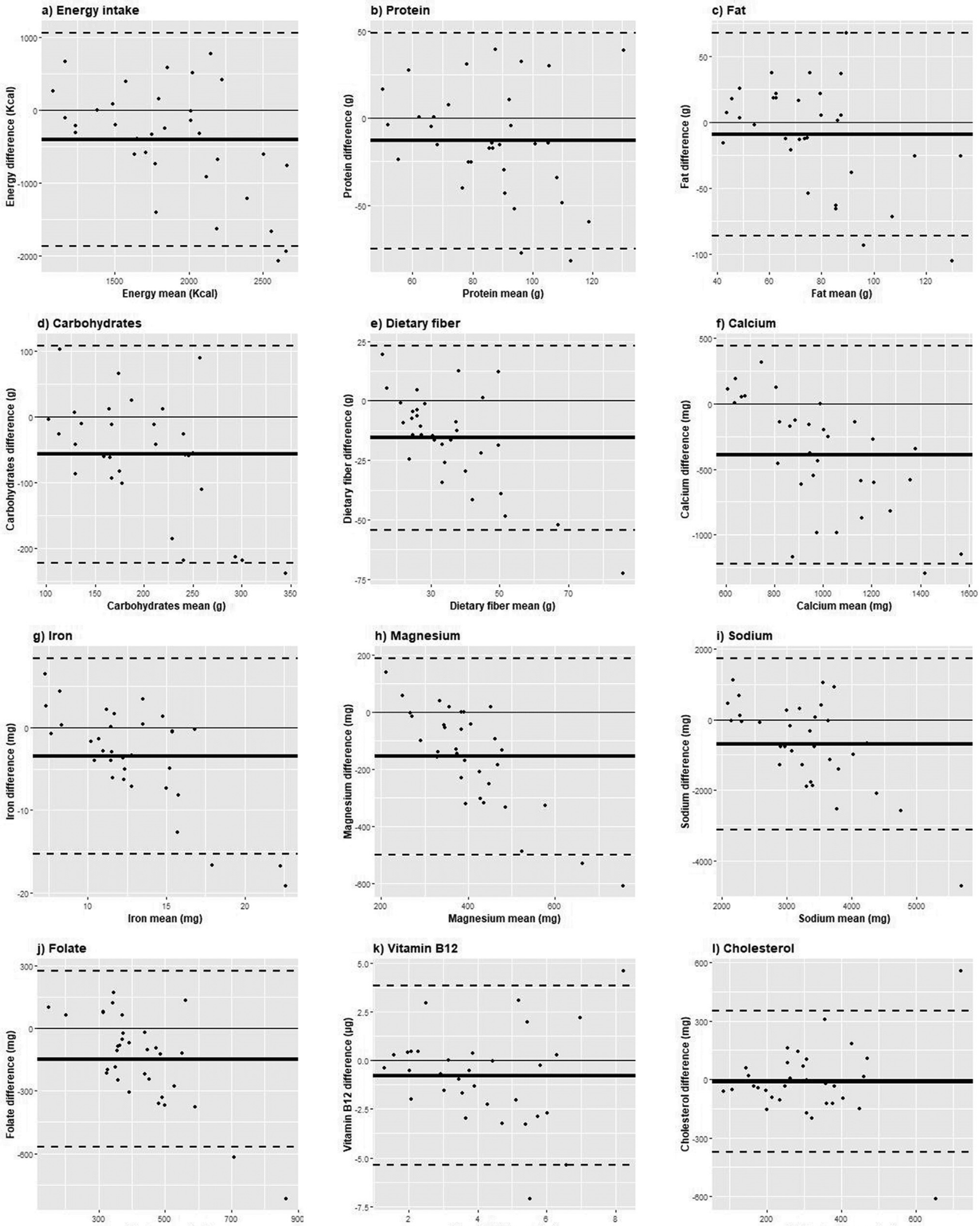

Fig. 5. Bland–Altman plots. Bland–Altman plots represent the agreement between the average nutrient intakes measured from FFQ1 and Mean 3d-DR. "Item difference" (y-axis) is the difference in "item" intake of FFQ1 minus that of the 24-h recall, while "item mean" (x-axis) is the mean of "item" intake by the two methods. The bold middle line represents the average difference between the two methods used (FFQ1 and Mean 3d-DR), while the upper and lower dashed lines represent the distance between the limits of agreement (±1.96 SD). (a) Bland–Altman analysis for energy intake; (b) Bland–Altman analysis for protein intake; (c) Bland–Altman analysis for fat intake; (d) Bland–Altman analysis for carbohydrates intake; (e) Bland–Altman analysis for dietary fiber intake; (f) Bland–Altman analysis for calcium intake; (g) Bland–Altman analysis for iron intake; (h) Bland–Altman

3.3. Reproducibility of food groups and level of processed food

Food groups and processed food scores derived from the computerized FFQ were evaluated for the 26 participants included in the reproducibility testing. Mean and standard deviation (SD) scores from both questionnaires are presented in Table 3. ICC between the two FFQs' food groups and processed food scores ranged from moderate, 0.53 (super processed food items), to high, 0.83 (non-processed food item) ($p < 0.05$). Spearman's correlations coefficient showed moderate to strong positive correlation, with correlations ranging from $rs = 0.58$ (sugar-sweetened beverage), to $rs = 0.79$ (non-processed food item) ($p < 0.05$).

3.4. Validity of food-frequency questionnaire

The Bland-Altman plots presented in Fig. 5 show a less satisfactory agreement between FFQ1 and the Mean 3d-DR due to the overestimation of FFQ1 [6,26].

A one sample t-test was performed to identify which of the variables has an acceptable agreement. Fat, vitamin B12, and cholesterol have acceptable agreement ($p > 0.005$).

4. Discussion

The purpose of this study was to validate a new computerized FFQ system based on the validated FFQs in Israel and the literature [1,34]. The FFQ validated in this study showed moderate to high reproducibility and acceptable validity in a group of women of fertility age. The validity of the FFQ was tested by comparing nutrient intake with Mean 3d-DR, while reproducibility was measured by repeating the submission of the FFQ.

The time interval between two FFQ submissions is essential in testing the reproducibility of a tool; shorter intervals between repeated FFQ submissions can contribute to the high reproducibility of FFQs. A low correlation between two submitted FFQs can arise naturally when eating habits and seasonal diet changes occur, which is more likely the longer the time interval between two FFQs is [41]. In this study, a time interval of two weeks was chosen to mitigate such factors.

To evaluate the reproducibility of the FFQ, ICC and Spearman's correlation coefficients were tested. The ICC reflects the reliability of measurements, and hence it expresses the extent to which measurements can be replicated. In our study, the ICC showed moderate to high reliability [37], as shown in other similar studies [42,43]. The reliability of the FFQ showed mostly moderate and acceptable correlation coefficients ranging from $rs = 0.47$ (calcium) to $rs = 0.67$ (carbohydrates & folate). These results are in the “adequate” range of 0.5–0.8, as proposed by Willet [34]. Furthermore, our values were higher than reported by Ogawa et al. [44]. Additionally, the reproducibility for food groups and processed food scores was good; the reliability of the FFQ exhibited mostly strong correlation coefficients ($rs > 0.7$), and the ICC showed mostly high reliability, similar to other studies [45,46]. The high reproducibility of food groups can enhance the study's total reproducibility and reflect suitable food groups' categorization of food items in our FFQ.

In terms of validity, most of the mean nutrient intakes reported by the FFQ were higher than those calculated based on the Mean 3d-DR, which is consistent with other past studies [4,26,43]. In addition, the tendency to overestimate FFQ data submission is reflected graphically in the Bland-Altman plots. The closer the mean of the difference is to zero, and the narrower the agreement interval is, the better the agreement between the two methods [47]. In our study, the Bland–Altman plots showed a less satisfactory agreement between the FFQ and the Mean 3d-DR for 9 out of 12 variables due to the wide agreement interval and FFQ overestimation. Other reasons for the differences between the FFQ and Mean 3d-DR could be the result of underreporting during the three days of 24-h DR or answering the three days of 24-h DR during holiday periods (which is frequent in diverse population countries such as Israel). In addition, perhaps a single week gup is too narrow of a period and therefore poorly reflected in the FFQ: we noticed that certain food groups that were reported by participants in the FFQ were unfortunately not mentioned at all in the 3d-DR. However, this could also be caused by the fact that the 24-h DR is often used as the reference method, while it may not truly be the “gold standard” [1]. The acceptable variables with good agreement were fat, vitamin B12, and cholesterol.

4.1. Strength and limitations

The size of the FFQ (133 food items) might have discouraged some participants from completing it. Perhaps funding for participation would have improved this issue. Another well-known and reported limitation is overestimated diet intake in FFQs; Even though FFQ overestimation may be the cause of the difference between the FFQ and the Mean 3d-DR, using this rapid and easy-to-implement tool is very cost-effective in large population studies. Even more so when the FFQ aims to find the relative dietary intake of an individual versus the population and not necessarily absolute quantitative consumption as the 24-h DR does. In relation to the 3d-DR, perhaps a 6-day DR over two weeks between the two FFQs, could bridge the gap between the two methods. In addition, we used women of fertility age for the study, and their diet has been reported to change around the menses [48]; perhaps controlling for the time in the menses in which the FFQ was filled out could have tackled this problem. However, that is not a realistic solution for logistic reasons. Additionally, women are reported to overestimate their food consumption, especially using FFQ [7], a problem that requires excluding outliers to minimize the difference between the two methods. Therefore, future validation of this FFQ system on a group of male participants may demonstrate an even better validity.

The present study also has several strengths; among them was the use of several statistical methods to assess the validity and reproducibility of our new computerized FFQ. The new computerized FFQ developed does not require an interviewer, a professional dietitian, or a trained researcher, and therefore interviewer bias is avoided. The use of visualized food portion sizes in the computerized FFQ may help to decrease overestimation compared to the Mean 3d-DR. Portion sizes, while being a strength, were limited to three, according to those adopted from research by the Ministry of Health for 24-h nutrition data recall [14–17]. In our study, overestimation in energy (Kcal) intake results for FFQ were similar to or lower than those of other research in the field [49–51]. Assessing dietary habits in the population can be challenging, especially since typical foods and dishes vary between cultures. However, our new computerized FFQ system enables easy database adaptation and a visual representation of foods and portion sizes, which both alleviate or circumvent such challenges altogether. Moreover, response quality improved by including cutoff values and alert messages in case of inconsistencies and abnormal or missing data. Additionally, the fundamental incorporation of the infrastructure that makes the translation of the FFQ to multiple languages possible is a great

analysis for magnesium intake; (i) Bland–Altman analysis for sodium intake; (j) Bland–Altman analysis for folate intake; (k) Bland–Altman analysis for vitamin B12 intake; (l) Bland–Altman analysis for cholesterol intake.

advantage. Furthermore, this new system can be quickly delivered to large populations via email or smartphone, with automatic result processing as soon as the questionnaires are submitted.

5. Conclusions

The objective of this study was to validate a new computerized Israeli FFQ. The new FFQ is flexible and easily adjustable to different research requirements, performs automated and immediate calculations, reports food processing levels, and has the added benefit of visualizing portion sizes.

Assessing dietary habits in the population can be challenging, mainly since typical foods and dishes differ between cultures and industrial food products differ between countries. However, our new computerized FFQ system provides a visual representation of foods and portion sizes and enables easy adaptation of the database, which should aid in circumventing these issues.

In conclusion, utilizing the rapid development of technology is compelling for the epidemiology research field as it enables more feasible and faster data collection tools. We offer a validated computerized FFQ that could improve cost-effectiveness for investigating dietary risk factors in nutritional research. To achieve higher validity, longer study periods, larger sample sizes, and more robust dietary records should be a focus of future research. Additionally, different gender and age groups should be explored.

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Author contribution

Shani Abutbul Vered – PhD student responsible for study coordination, writing, and approval of the final manuscript as submitted.

Carmit Shani Levi – research assistant, writing and approval of the final manuscript as submitted.

Gydeon A. Rozen – research assistant, proofreading and editing, writing, and approval of the final manuscript as submitted.

Ido Solt – chief investigator for Helsinki committee approval and MD for study population and approval of the final manuscript as submitted.

Geila S. Rozen – research plan, clinical work with participants in both groups, academic supervision, and writing and approval of the final manuscript as submitted.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Declaration of competing interest

The corresponding author states, on behalf of all authors, that there is no conflict of interest.

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Risk factors for Early Childhood Caries in Italian preschoolers: A cross-sectional analysis


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Abstract

Aim Early childhood caries (ECC) represent a relevant public health issue in paediatric population globally. The current study aimed to investigate the main risk factors of this condition.

Study design and methods This is a cross-sectional study carried out at the Child Dentistry Clinics of the Istituto Stomatologico Italiano, Milan, Italy, including patients aged 12-71 months and their parents. Demographical data, anthropometric measurements, oral hygiene and health assessment, and children's eating habits were collected.

Results An ECC prevalence of 72% was found. Oral hygiene practices resulted inadequate. Moreover, we found fruit juice consumption among children's eating habits higher than 3 times/week. Mother's educational level, prenatal passive smoking, child's eating behaviour such as the introduction of sugar-sweetened beverages (SSBs) before the age of 12 months and the number of SSBs drunk before the age of 24 months, and child's oral hygiene in terms of the start of teeth brushing (i.e., after 12 months of age) were correlated to dmft. The binomial logistic regression analysis confirmed a positive association between dmft and the mother's educational level (OR=2,36, CI 95%= 1,26 - 4,4, p=0,007).

Conclusion Our findings, according to recommendations, suggest that the prevention of ECC needs to begin in infancy. Oral health providers, physicians, nurses, and other health care personnel play an important role in educating parents about their child's oral and dental care and food choices.

KEYWORDS Early childhood caries, sugar-sweetened beverages, breastfeeding, maternal education, oral hygiene.

Introduction

Early childhood caries (ECC) is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing, or filled (due to caries) surfaces in any primary tooth of a child under six years of age [Drury et al., 1999]. ECC represents a relevant disease in the paediatric population worldwide, affecting 48% of global preschool children [Uribe et al., 2021]. In Italy, research conducted in 2018 on 3000 children aged between 0 and 71 months showed a prevalence of caries equal to 2.9% in subjects aged 0–23 months, 6.2% in those 24–47 months, and 14.7% in those 48–71 months [Colombo et al., 2019]. Consequences on health and quality of life can be numerous and severe, such as dental malocclusion, progression of tooth decay, enamel defects, pain, dental emergencies, potential changes in growth and development, difficulty sleeping, low academic performance, etc. Traditional microbial risk markers for ECC include Streptococcus mutans and Lactobacillus species [Kanasi et al., 2010; Liu et al., 2019]. ECC is an infectious disease characterised by vertical transmission (from parents to child) and horizontal transmission (between members of a group) [Poureslami and Van Amerongen 2009]. Furthermore, ECC shares common risk factors with other non-communicable diseases (NCDs), such as cardiovascular disease, diabetes, and obesity. In particular, the high consumption of sugary food and beverages increases the risk of overweight/obesity as well as tooth decay in paediatric populations [Fidler et al., 2017; Muth et al., 2019]. Additionally, the incidence of tooth decay in overweight and obese children is higher than in those of normal weight [Manohar et al., 2020]. Hence, strategies for preventing tooth decay are aimed at achieving accurate oral hygiene and adequate eating habits from childhood, i.e., limited consumption of sugar-sweetened beverages (SSBs) and refined foods [Bhoopathi et al., 2024]. In this context, parents may play a crucial role by providing their children with healthier behaviours and food choices [Minervini et al., 2023]. To date, gaps in the knowledge of behavioural factors that cause ECC in the first years of life and pre-school age exist. The current study aims to identify the main risk factors underlying ECC in the first years of life, to plan efficient and effective preventive strategies to reduce ECC onset and progression, with a specific focus on the eating habits of children up to 6 years old.

Methods

This is a cross-sectional study conducted, between June 2022 and June 2023 at the Maternal and Child Dentistry Clinics of the Istituto Stomatologico Italiano (ISI), Milan, Italy. This work was approved by the Ethics Committee of the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan [Protocol number: 6151; Date: 13 Maggio 2022]. The inclusion criteria were: patients aged 12-71 months, belonging to the

VISUAL ABSTRACT

Summary

Early Childhood Caries (ECC) is a major public health issue worldwide. Risk factors include poor oral hygiene, delayed toothbrushing, frequent sugary drinks, high maternal education, and exposure to secondhand smoke during pregnancy. Therefore, the prevention of ECC should begin in infancy.

Study design

Cross-sectional study

June 2022-June 2023

4 questionnaires assessed children's early dietary habits, anthropometric data of children and caregivers, children's eating behavior (CEBI), and the oral hygiene of both children and caregivers

Population

children & parents	children aged	mean age	
171	**12-71** months	**54** months	**42** % female

patients referred to Child Dentistry Clinics of the Istituto Stomatologico Italiano, Milan, Italy

Outcomes

The study examined ECC and its associated risk factors

Delayed start of oral hygiene in children

p = 0.005

Introduction of sugar-sweetened beverages before 12 months

p = 0.014

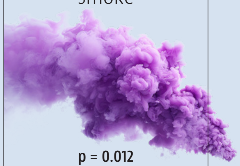
The number of sugary drinks consumed before 24 months

p = 0.005

High maternal education level

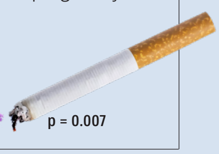
p = 0.004

Fathers' secondhand smoke



p = 0.012

Number of cigarettes smoked during pregnancy



p = 0.007

All parents should be given dietary education during pregnancy, and nutritional counseling is crucial when ECC is present.

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ISI Maternal and Child Dentistry Clinics, and written informed consent of legal caregivers. The study was proposed to the parents (or guardians) of each patient during the dental visit and informed consent was obtained.

Demographical data

Centrally trained personnel interviewed parents to obtain information on general socio-demographic characteristics and health history of their child. Furthermore, parents' smoking, reported weight and height were recorded.

Anthropometric measurements

Child body weight was measured using a gram scale (Tanita TL-150 MA; Sensor Medics, Milano, Italy), accurate to 0.1 kg. Child length (12-23 months) was measured with an infantometer (SECA 416, Hammer Steindamm 3-25 22089 Hamburg Germany) and height was measured with a stadiometer (SECA 213, Hammer Steindamm 3-25 22089 Hamburg Germany). Body mass index (BMI) was calculated as weight (kg) / length or height (m^2). The World Health Organization (WHO) Anthro and Anthro Plus® software and the WHO reference charts were used to calculate Z-scores and percentiles for weight for age, BMI, and weight for length [Blossner et al., 2009]. WHO criteria were referred to classify child nutritional status [Onis et al., 2007].

Oral hygiene and health assessment

The dental examinations were carried out by a trained dentist by using the International Caries Detection and Assessment System criteria, with a flat-surface mouth mirror, a dental explorer, compressed air and lamp lights [Cianetti et al., 2017]. Then, the decayed-missing-filled-teeth (dmft) was recorded. Oral hygiene was investigated in children and parents enrolled by ad hoc case report form. Specifically, parents were asked about their caries or dental problems, daily frequency of brushing teeth, and knowledge of caries' transmissibility. Moreover, they were interviewed about their children's oral hygiene habits both at home and at school.

Children's eating habits

Early life habits were investigated through an ad hoc questionnaire to record breastfeeding duration, formula introduction, night feeding, complementary feeding, and SSBs introduction.

Statistical analysis

Assuming an ECC prevalence of 8,2% [Colombo et al., 2019] in children aged 12-71 months, a sample size of 157 subjects was necessary to achieve a precision of 5% with a 95% significance level. Categorical or ordinal variables were expressed as frequency (percentage, %); continuous variables

	No	%
Baseline characteristics		
Age (years), mean (SD)		4.6 (±1.1)
Female	71	42
Ethnicity		
Caucasian	158	92.3
Hispanic	8	4.7
Asian	4	2.3
African	1	0.6
Type of delivery		
Vaginal	124	72.5
Dystocic	10	5.8
Induced	2	1.2
Caesarean	35	20.5
Birth weight < 2500 g	10	5.8
Preterm	5	2.9
Anthropometric measurements		
Weight in kg mean (±SD)		17.6 (±3.0)
Length/height in m		1.1 (±0.1)
Nutritional status		
Normal weight	134	78
Overweight	12	7
Obese	1	1
Underweight	24	14

TABLE 1 General and anthropometric characteristics of children (n=171).

		Mother	Father
Age (mean ± SD)		38.2 (±5.8)	41.3 (±7.2)
Educational level			
	Master degree/ PhD	87 (51)	59 (35)
	High school	62 (36)	80 (48)
	Secondary	22 (13)	29 (17)
Job	No	29 (17)	2 (1)
Smoking			
	Currently	43 (25)	49 (29)
	During pregnancy	9 (5)	44 (26)
BMI (mean, SD)		23.1 (±4.5)	25.7 (±3.5)
	Normal weight	111 (65)	81 (48)
	Underweight	17 (10)	1 (1)
	Overweight	30 (13)	65 (39)
	Obese	13 (8)	20 (12)

TABLE 2 Socio-demographic and anthropometric characteristics of mothers (n=171) and fathers (n=168) of the study population.

Parents		N (%)
Caries o dental problems (number)		
	≥7	28 (17)
	4-6	45 (26)
	1-3	60 (35)
	0	38 (22)
Parents' oral hygiene / brushing teeth (times/day)		
	1	19 (11)
	≥ 2	152 (89)
Parents' knowledge on caries' transmissibility		
	Yes	53 (31)
	No	118 (69)
Children		
Age at first visit (months; mean ± SD)		38.5 (±12.3)
Reason		
	Dental pain	60 (35)
	Dental trauma	28 (17)
	Check-up	62 (36)
	Suggested	20 (12)
Start of brushing teeth (months)		
	0-12 (before)	16 (9)
	0-12 (after)	68 (40)
	12-23	52 (31)
	24-48	31 (18)
	48-72	3 (2)
School attendance		
	Yes	163 (95)
	No	8 (5)
Brushing teeth at school		
	Yes	11 (7)
	No	159 (93)
Use of toothpaste		
	Yes	162 (95)
	No	8 (5)
Use of fluoride toothpaste		
	Yes	151 (89)
	No	19 (11)
Use of SSBs before sleeping		
	Yes	7 (4)
	No	164 (96)
Use of SSBs during the day		
	Yes	9 (5)
	No	162 (65)
Use of pacifier with sugar or honey		
	Yes	7 (4)
	No	164 (96)
Oral hygiene / brushing teeth (times/day)		
	< 1	2 (1)
	1	32 (19)
	2	117 (69)
	3	19 (11)
Children with dmft = 0		48 (28)
dmft (mean ± SD)		3.8 (±4.4)

TABLE 3 Dental Problems and Oral Hygiene Behaviour.

as mean and standard deviation, if normally distributed, and as median and interquartile range if not. Within-group and between-group comparisons were performed with parametric or non-parametric statistical tests, where appropriate: for comparisons between groups, Student's t-test (2 groups) or ANOVA (>2 groups) was used for distributed continuous variables typically, the Mann-Whitney test (2 groups) or Kruskal-Wallis test (>2 groups) for asymmetrically distributed continuous variables, the Chi-square test or Fisher's exact test (where appropriate) for categorical variables. We conducted a binomial logistic regression analysis to examine the association between parents' characteristics (maternal and

	mean (±SD)
Infancy feeding	
Duration (months)	
Exclusive breastfeeding	5.9 (±6.8)
Predominant breastfeeding	8.0 (±7.3)
Night feeding	10.0 (±8.8)
Milk-Bottle feeding	26.2 (±13.9)
Water bottle feeding	19.3 (±8.7)
Age of introduction (months)	
Infant Formula (IF)	3.2 (±3.0)
Formula (Growing-up milk)	13.5 (±5.9)
Cow milk	16.4 (±9.1)
Complementary food - Starting	6.2 (±1.7)
Minced textured food	8.8 (±3.6)
Chopped textured food	12.5 (±2.9)
Family food	17.8 (±8.9)
Self-eating (months)	16.5 (±8.6)
Age of introduction of SSBs (years)	2.2 (±1.3)
Frequency of consumption SSBs (times/ week)*	
Fruit juice	3.2 (±2.9)
Herbal tea	0.4 (±1.2)
Tea	0.6 (±1.8)
Chamomile tea	0.4 (±1.3)
Current feeding habits	
Meals (number/day)	4.8 (±0.6)
Night feeding (%)	
Yes	3.0
No	95.0
Sometimes	2.0

* Evaluated in n= 144

TABLE 4 Feeding practices in the study population.

paternal BMI separately) as explanatory variables and children's dmft (=0 or >1) as outcome. The following were also used as variables: frequency of consumption of fruit juice, herbal tea, tea, and chamomile tea, and number of cigarettes smoked both by mother and father and the educational level of the mother. Covariates have all been included independently in separate models. Logistic regression models of dmft >1 in children according to parents' characteristics and habitual consumption. The level of statistical significance was set at a p-value < 0.05 and, where appropriate, 95% CIs have been calculated.

Results

Out of 176, a total of 171 participants were enrolled. The mean age (± standard deviation, SD) was 4.6 (±1.1) years, 42% were females (Table 1). Most children were delivered at term (97%), vaginally (72%), and with an adequate weight (94%). Concerning nutritional status, 78% were sufficiently nourished. Table 2 describes the parents' characteristics. On average, mothers were 38.2 (±5.8) years old and fathers 41.3 (±7.2). Most parents were employed and the mothers showed the highest educational level. At least a fourth of parents were smoking at the time of the survey. Regarding the family composition, 26% had one child, 60% had 2 children while only 8%, 5%, and 1% had 3, 4, and 6 children, respectively. Considering the nutritional status, 65% of the mothers and 48% of fathers were normal weight.

Oral health and behaviours

We found a 72% prevalence of ECC. The data about dental problems and oral hygiene are reported in Table 3. Considering parents' characteristics, only 22% did not show any dental problems, 31% considered caries as transmissible, and 89% brushed their teeth ≥ 2 times daily. Toddlers and children (n=133) showed a mean dmft score of 3.8 (± 4.4), and 100 of them started drinking SSBs before the age of 24 months. Nine percent of parents cleaned their child's mouth before tooth eruption, 40% of them started brushing their baby's teeth after the eruption of the first tooth by the 12th month of age, and the remaining after. Moreover, most parents brushed their baby's teeth twice a day (69%) and used fluoride toothpaste (95%). The majority of children (93%) did not brush their teeth at school. The age at the first visit was 38.5 (± 12.3) months, mostly due to pain or check-up.

Children's eating habits

Feeding practices are reported in Table 4. The mean duration of exclusive breastfeeding was 5.9 (± 6.8) months, that of predominant breastfeeding was 8.0 (± 7.3) months, and the night feeding duration was 10.0 (± 8.8) months. Complementary food was introduced at 6.2 (± 1.7) months. Regarding drink consumption, fruit juice was the most frequently drunk with a mean of 3.2 (± 2.9) times/week with a mean age at the time of introduction of 2.2 (± 1.3) years.

Risk factors and dmft

We found a significant correlation between the child's dmft and the mother's educational level (ρ=0.218; p=0.004), the father's smoking status (ρ=0.193; p=0.012) and the number of cigarettes (ρ=0.208; p=0.007) during pregnancy, the child's start of teeth brushing (ρ=0.213; p=0.005), the child's introduction of SSBs before the age of 12 months (p=0.014), and the number of SSBs drunk before the age of 24 months (ρ=0.232; p=0.005). Furthermore, the mother's educational level correlated with the child's start of teeth brushing (ρ=0.234; p=0.002) and the child's daily frequency of teeth brushing (ρ=-0.170; p=0.028). No correlation was found between night feeding after the age of 12 months and the dmft. The binomial logistic regression analysis confirmed a positive association between dmft and the mother's educational level (OR=2,36, CI 95%= 1,26 - 4,4, p=0,007).

Discussion

Adequate oral hygiene and eating habits are crucial for preventing early tooth decay, i.e., ECC which represents a relevant disease in the paediatric population worldwide. Some findings deserve consideration.

Oral health and behaviours

In our population, the prevalence of ECC resulted in 72%. This high prevalence could be explained by the fact that children were recruited from the ISI, considered a second-level centre providing advanced care and treatments in dentistry and oral surgery. The Italian Clinical Recommendations in Odontostomatology [Italian Ministry of Health, 2017] indicate that children should have their first dental examination between 18 and 24 months of age. In contrast, we found that the age of the first visit occurred beyond 1 year later than recommended. This concerning result may be partly due to a lack of guidance provided to parents by children's healthcare professionals [Colombo et al, 2023]. In our population, only 12% of the parents reported being advised to make a dental visit. Likewise, previous data reported that less than 1% of parents took their children to the dentist based on advice from healthcare providers, including paediatricians, pharmacists, and general practitioners [Colombo et al., 2019]. This trend suggests that there is a need to promote dental visits to be undertaken as early as possible [Sanguida et al., 2019; American Academy of Pediatric Dentistry, 2023; Ilisulu et al, 2024]. In accordance with Colombo and colleagues [2019] detecting that more than 80% of parents were unaware that caries could be an infectious and transmissible disease, we found that almost 70% of the parents did not know that tooth decay is a transmissible disease. Advising parents/primary caregivers about the importance of their oral health and the possible transmission of cariogenic bacteria from them to the child is crucial to preventing the disease [Paglia et al., 2016]. Similarly, caregivers should be educated about oral hygiene practices which should ideally commence from birth as cleaning of gums after each feeding, becoming crucial when infants start eating solid food (around 6 months of age) [Shrestha et al., 2024]. According to our results, only 9% of parents cleaned their child's mouth before tooth eruption whilst almost half of the children started teeth brushing after 12 months of age suggesting a potential involvement of poor oral hygiene practices in the prevalence of ECC observed. In contrast with the trend observed in existing literature which highlights that a higher maternal educational level likely protects against ECC [Ferrazzano et al, 2019; Folayan et al., 2024], we found a positive association between the maternal education level and the child's dmft. This result could be explained by considering that higher educational attainment may be related to more demanding work that leads to reduced hygienic dental care of the child. Indeed, we observed that the mother's education correlated positively with the child's start of teeth brushing while inversely with the child's daily frequency of teeth brushing: mothers with higher education had likely children who started brushing their teeth later and brushed less frequently. Furthermore, we found a positive correlation between the mother's exposure to passive smoke generated by the father during pregnancy and the child's dmft in line with the results from a recent systematic review reporting increased susceptibility to dental caries among the children exposed to prenatal smoking [Uthayakumar et al., 2023]. It has been hypothesized that passive smoking during the prenatal tooth formation can affect the enamel mineralisation process thereby favouring developmental enamel defects, that are more susceptible to cariogenic bacteria in the presence of sugars [Akinkugbe et al., 2020].

Children's eating habits

In our population, the length of exclusive breastfeeding and the age of introduction of complementary feeding were in line with recommendations [WHO, 2021], the majority of the children did not consume night meals, and the habit of both nocturnal meals and breastfeeding lasted less than 12 months. The association between breastfeeding and ECC is one of the most debated risk factors for ECC, as existing evidence remains inconclusive and equivocal. However, a recent meta-analysis failed to evidence a statistically significant difference in dental caries rates between breastfed and non-breastfed children, even if breastfeeding extended beyond 12 months and nocturnal breastfeeding increased the risk of ECC [Shrestha et al., 2024]. It might be that breastfeeding, particularly when occurring at night, contributes to ECC because the milk remains in the baby's mouth for extended periods not because human milk is cariogenic. As expected considering our findings, that is most of the children did not consume night meals and the habit of both nocturnal meals and breastfeeding lasted less than 12 months, no correlation was detected between night meals or breastfeeding length and dmft. Alarmingly, the consumption of fruit juice being higher than 3 times/week did not meet the recommendation by the Società Italiana di Pediatria and Società Italiana di Endocrinologia e Diabetologia Pediatrica to avoid sugary drinks in the first 2 years of life [Giuliana et al., 2018]. Moreover, the American Academy of Pediatrics recommends not to introduce fruit juice to infants before 1 year of age while admitting the consumption of 120 mL (nearly a glass) daily of fruit juice among toddlers but only as part of a meal or snack [Heyman et al., 2017]. A high consumption of SSBs early in life, that is free sugars appears to contribute to the development of caries [Severino et al., 2021; Large et al., 2023] which may at least partially explain the high prevalence of ECC in our population. This study showed some limitations. Firstly, the cross-sectional design prevented the causal relationship between the ECC and identified risk factors. Moreover, data may be influenced by sampling bias. The sample under examination was indeed representative of a narrow segment of the population, including children who accessed the Maternal and Child Dentistry department at the ISI, thereby potentially at increased risk of dental problems. Furthermore, data obtained from parents were subject to recall bias. Finally, the accuracy of the information regarding children eating habits could be also compromised as their meal consumption did not always occur under parental supervision (i.e. school, other caregivers). However, the study was of interest because it addressed a prevalent public health issue, specifically ECC in preschool-aged children and only a few Italian studies deal with it. Moreover, a broad spectrum of risk factors, such as demographic characteristics, dietary habits, oral health status, and parental behaviours, was investigated, providing a holistic view of the issue.

Conclusion

In our population of children aged 12-71 months, the prevalence of ECC was high, but parents often lack sufficient knowledge about this alarming issue. ECC is a disease with potentially harmful consequences on the child's health in the short- and long-term. Based on the results of this study, it is necessary to promote effective informational campaigns on the determinants of the early spread of carious disease and the exponential growth of ECC, including prenatal smoking. In particular, oral health providers, physicians, nurses, and other health care personnel play a crucial role in perinatal and infant oral health, as they may contribute to raising awareness about proper oral hygiene by educating parents, determining the correct timing for a child's first dental visit, and establishing a dental home routine. Moreover, it is pivotal to disseminate information about adequate dietary habits early in life. Given the link between excessive sugar intake, NCDs and ECC, this condition can be considered an early indicator of dietary errors. Therefore, educational interventions aimed at reducing free sugar intake in childhood could be part of a broader program for the prevention of NCDs in adulthood.

Abbreviations

BMI: Body Mass Index
ECC: Early Childhood Caries
dmft: decayed-missing-filled-teeth
ISI: Istituto Stomatologico Italiano
NCDs: non-communicable diseases
SSBs: Sugar-Sweetened Beverages
WHO: World Health Organization

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MDPI

Article

The Mediterranean Diet in Osteoporosis Prevention: An Insight in a Peri- and Post-Menopausal Population

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Abstract: Osteoporosis represent a widespread public health problem. The management and prevention of osteoporosis and related low energy fractures start with a correct lifestyle and proper nutrition. Several different nutrients are essential for bone and mineral metabolism, especially calcium. Nevertheless, a well-balanced nutrition, such as Mediterranean diet (MD), proved to be beneficial for several chronic diseases and also fragility fractures resulted lower in the Mediterranean area. A prospective observational study in a population of two hundred peri- and post-menopausal women (aged 30–80 years) was developed at Careggi hospital, Florence. Both MD adherence and dietary calcium intake were evaluated in occasion of a "first visit" and a "follow-up" visit, through validated questionnaires. From a descriptive point of view, although not statistically significant, in both visits a slight increase in calcium intake was observed for high adherence to MD diet. Moreover, a short nutritional interview (20 min) was applied in our population and demonstrated to be sufficient to significantly improve MD adherence level (mean score at T_0 = 6.98 ± 1.74 and T_1 = 7.53 ± 1.68), opening promising paths in osteoporosis prevention.

Keywords: osteoporosis; Mediterranean diet; calcium intake; menopause; bone health

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1. Introduction

Osteoporosis (OP) and fragility fractures represent a public health problem in western countries, involving a large part of the population and steadily increasing worldwide. In fact, OP is a chronic condition that can require long-term management, and the World Health Organization (WHO) describes it as a "progressive systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture" [1].

Globally, OP affects over 200 million individuals. Hernlund E. et al. reported in 2010 that, in the European Union, approximately 6% of men and 21% of women aged 50–84 years have osteoporosis, affecting 27.6 million men and women [2].

In Italy, it is estimated that there are about 3.5 million women and 1 million men suffering from OP. Given that the percentage of the Italian population over 65 years of age will increase by 25% over the next 20 years, we can expect a proportional increase in the incidence of osteoporosis [3].

Low-energy fractures, typical of osteoporosis, represent the main clinical evidence of disease progression. Major fragility fractures (especially hip fracture) increase mortality risk in all ages, and in older age also minor fractures increase the risk [4].

Tarantino et al., in their study based on a three-year multicenter survey, estimated that in Italy there is an annual incidence of 410,000 new hip, humeral, wrist, ankle, and vertebral fragility fractures. The authors observed that about 70% of the overall fractures observed during the study period occurred in persons aged older than 65 years, and 87% were classified as fragility fractures [5].

Management and prevention of osteoporosis and related low energy fractures starts with a correct lifestyle, that includes smoking abstention, daily physical activity, low alcohol consumption and proper nutrition. In this manuscript, we will analyze the relationship between Mediterranean diet, calcium intake and bone health. The results from a prospective cohort study, considering a population of peri- and post-menopausal women, will be reported, in order to clarify the relationship between diet and bone health, with the aim to examine Mediterranean diet adherence level and dietary calcium intake.

Background

Diet is of critical interest in osteoporosis because it is one of the few safely modifiable risk factors. Healthy, well-balanced nutrition can play an important role in the prevention and pathogenesis of osteoporosis, and in support of pharmacological therapy [6]. Several factors contribute to the development of osteoporosis in post-menopausal women, among which, low-grade inflammation, poor dietary habits, and sedentary and unhealthy lifestyles, such as smoking and alcohol consumption [7,8].

Calcium is the main actor in bone health. It is the principal component of the mineralized bone matrix where more than 99% of the total body calcium is contained; its key role in maintaining bone health throughout life has been recognized by many studies. An optimal dietary calcium intake is necessary for bone health at all stages of life: In children and adolescents to contribute to the formation of a healthy skeleton, and in adults and the older adults to allow the maintenance of adequate bone mass [9,10]. Dietary requirements for calcium are determined by the need for bone development and maintenance; therefore, Recommended Dietary Allowance for Calcium varies throughout life. As stated both at the international level by the Institute of Medicine of the National Academy of Sciences (IOM) [11], and at the Italian level by the Reference Levels of Nutrients and energy intake for the Italian population (LARN, Livelli di Assunzione di Riferimento di Nutrienti ed energia per la popolazione italiana) (Tb.1) [12], the recommended daily requirements of calcium are 1000 mg for adults (male and female) and 1200 mg for subjects older than 65 years, teens, and those who suffer from osteoporosis.

Nutritional intake is the preferred method for calcium acquisition, because it allows the introduction of small quantities of the mineral throughout the day. This way, its absorption is optimized, avoiding oscillator spikes that could lead to cardiovascular complications [13].

Although dietary calcium intake is essential for skeletal health, a recent review by the International Osteoporosis Foundation (IOF) showed that, in 74 countries around the world, average calcium intake ranges between 175 and 1233 mg/day, with values sometimes much lower than those recommended for the adult population. Only in northern Europe do the average values exceed 1000 mg per day [14]. In Italy, the 2005–2006 INRAN-SCAI study on women and men aged from 18 to 65 years reported that the average calcium intake in the male population was 799 $\pm$ 337 mg/day, while for the female population it was 730 $\pm$ 277 mg/day, both below the LARN recommendations for adults [15].

Over the last 20 years, numerous epidemiologic and experimental studies in nutrition have focused on the Mediterranean Diet (MD), because it is well-known for its health benefits and protection against several chronic western diseases (cardiovascular and metabolic diseases) [16,17].

The incidence of OP and fragility fractures is very variable in the countries of the European Union, but it has been observed that it is lower in the Mediterranean area [18]. The CHANCES project [19], the EPIC [18] and the EPIC-older study [20], the Women's Health Initiative [21], and some Swedish population studies [22,23], report that the incidence of fragility fractures is lower in subjects with a diet more adherent to the Mediterranean pattern.

However, a direct cause-and-effect association between adherence to the MD and a reduction in fragility fractures incidence has not been demonstrated.

Recently, scientific literature reviews have confirmed that greater adherence to the MD is associated with a reduced total fracture risk and higher bone mineral density (BMD) [24].

However, the beneficial effect of the Mediterranean diet on skeletal health is more controversial when the observational studies are analyzed as a whole. A review by Kunustor et al. reports that there are still limited observational studies that support beneficial effects of adherence to the Mediterranean lifestyle on the incidence of hip fractures [25].

Despite the conflicting results, interest in studying the impact of nutrition and, in particular, of MD on bone health, is still very high. A recent longitudinal cohort study by Benetou et al. examined 140,775 adult subjects from five cohorts (Europe and the United States) to assess the level of adherence to the MD and the incidence of fractures. From this population, it emerged that the incidence of hip fracture was lower in those with medium and high levels of adherence to MD than in those with low adherence [26].

The traditional Mediterranean diet is characterized by a high intake of vegetables, legumes, fruits and nuts, cereals (which, in the past, were largely unrefined), a high intake of olive oil (and a low intake of saturated lipids), a moderately high intake of fish (depending on the proximity to the sea), a low-to-moderate intake of dairy products (mostly in the form of cheese or yogurt), a low intake of meat and poultry, and a regular but moderate intake of ethanol, primarily in the form of wine during meals.

Current research shows that the consumption of food groups typical of the Mediterranean diet, such as fruit, vegetables, low-fat dairy products, and fish, is essential for maintaining good bone health [27–30].

The use of extra virgin olive oil (EVOO) as the main source of fat has been shown to be beneficial in preventing bone loss, probably due to the high content of polyphenols. An in vitro study by García-Martínez et al. shows that EVOO phenols can modulate the cellular proliferation and maturation of osteoblasts, increasing the activity of alkaline phosphatase and depositing calcium ions in the extracellular matrix [31].

However, few studies have been performed on humans. Fernández-Real et al. evaluated the effects of olive oil consumption on circulating levels of osteocalcin (OC). An MD enriched with EVO, administered to the subjects for two years, was associated with a significant increase in blood OC and concentrations of the N-terminal pro-peptide of type 1 procollagen, suggesting a protective effect on the bone [32].

The results in an additional study, although preliminary [33], show a well-defined image of the health properties of MD on prevention and slowing progression of chronic degenerative diseases, including OP.

2. Materials and Methods

Starting from this background knowledge, our group performed a study to clarify the relationship between diet and bone health, specifically in a female population characterized by several variables. In particular, the aim of the study was to examine Mediterranean Diet (MD) adherence level and dietary calcium intake in peri- and post-menopausal women who visited the Bone and Mineral Metabolism Unit in Careggi Hospital, Florence, in order to investigate the role of the MD for bone health maintenance.

2.1. Subjects and Procedures

A prospective, observational, monocentric, spontaneous, no-profit study was performed in Careggi Hospital, Florence, Italy, from September 2017 through August 2018. The study was approved by the Institutional Review Board (Comitato Etico Area Vasta Centro, Azienda Ospedaliera Universitaria Careggi, Florence, Italy) [number: 11097_oss]. The Ethics Committee verified the conformity to the *Good Clinical Practices* and to the Declaration of Helsinki. All patients gave informed consent for participation in the study and consent for data publication.

Two hundred peri- and post-menopausal women, age range 30–80 years, were recruited upon their "First visit" to the Bone and Mineral Metabolism Unit (Careggi Hospital, Florence). The exclusion criteria included: Pregnancy and breastfeeding, and participation in other studies. Figure 1 shows the recruitment procedures. Recruited subjects were evaluated a second time in occasion of a "Follow-up visit". The time distance between "first visit" and "follow-up visit" was variable from one to twelve months and was decided by the specialist on the basis of the "first visit" results and each subject's needs.

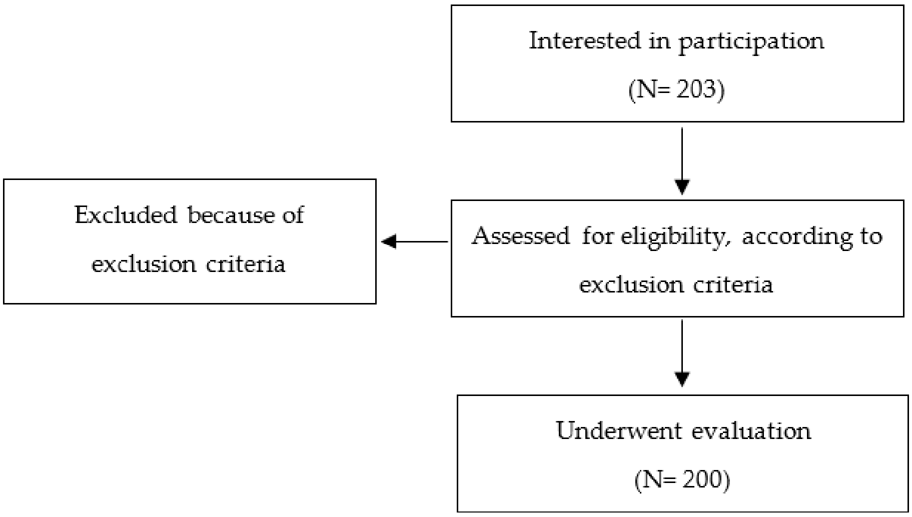

Figure 1. Flow chart showing a description of study design, recruitment and assessment.

In occasion of the "First visit" to the Unit, a trained nutritionist presented the study and gave the documents necessary for participation (patient information pack, informed consent, and consent for data handling), which were then signed by the participants. Information regarding socio-demographic data, clinical assessment (pathologies, medical treatments or supplement use), lifestyle habits (physical activity index, smoking habit), were then recorded.

The nutritional investigation was performed through two specific questionnaires. First, a 14-item questionnaire was administered to evaluate MD adherence level, examining the consumption of typical Mediterranean food, such as olive oil, fruits and vegetables, and legumes [34]. One point was assigned to each correct Mediterranean diet behavior, and the total score ranged from 0 to 14: A total score equal to or under five corresponded to low MD adherence, between 6 and 9 medium MD adherence, and equal to or above 10 high MD adherence.

Second, a semi-quantitative Food Frequency Questionnaire (FFQ) was administered to evaluate calcium intake. The questionnaire consisted of 15 food items, including: milk and dairy products, fruits, vegetables, legumes, cereals, meats, fish, eggs, and calcium-rich mineral water [35]. Subjects were asked to report consumption frequency and portion size assessment. Calcium intake was assessed by a specific worksheet, using Microsoft Excel 2010 software, which reported the calcium content of each food, referring to Food composition Tables of the Centre of Research for Food and Nutrition [36] and Food Composition Database for Epidemiological Studies in Italy of the European Institute of Oncology [37].

A trained nutritionist performed the evaluation and data collection procedures. After that, the nutritionist gave dietary advices of *good clinical practice* to the participants. In particular, a short conversation (15–20 min) was dedicated to advice for good dietary habits for bone health, focusing on calcium intake and improving MD adherence.

During the "Follow-up visit" at the Unit, information regarding medical treatment and/or supplements, blood sample results, instrumental exams, and lifestyle habits were collected again. The nutritional evaluation was also repeated. Anthropometric measurements (weight, height, waist circumference) and body composition evaluation (Fat Mass, Fat Free Mass, Total Body Water) were recorded during both visits. Body composition was measured through bioelectrical impedance analysis (BIA) device (BIA 101 Anniversary by Akern Srl, Firenze, Italy with the Bodygram 1.31 software and its equations by Akern Srl, Firenze, Italy).

2.2. Statistical Analysis

Descriptive statistics (i.e., mean and standard deviation, percentages of frequency) were used to summarize socio-demographic characteristics and anthropometric values.

Paired sample t-test was applied to evaluate the MD adherence score at T0 ("First visit") and T1 ("Follow-up visit"). McNemar test was run to compare answer frequencies (%) to MD adherence questionnaire and FFQ at T0 and T1.

Chi-square analysis was used to assess the proportion in each group of the degrees of MD adherence and of adequate calcium intake, at T0 and T1. Adequacy of calcium intake was considered respect to Population Reference Intake (PRI) for the Italian population, reported by the Italian Society of Nutrition (SINU) in the Levels of Reference Consumption of nutrients and energy (Livelli di Assunzione di Riferimento di Nutrienti ed energia-LARN), (SINU, 2014) [12].

Statistical significance was considered $p < 0.05$. Analyses were performed using IBM SPSS Statistics for Windows, Version 20.0. (Armonk, NY, USA: IBM Corp.).

3. Results

Two hundred women were recruited. One hundred seventy-two (86%) were also evaluated at T1. The socio-demographic characteristics and lifestyle habits of the whole population at T0 and T1 are summarized in Table 1. The mean age at T0 was 61.60 ± 8.77 and at T1 was 61.72 ± 8.25.

Table 1. Socio-demographic characteristics and lifestyle habits of the population at T0 and T1, descriptive statistics (percentages of frequency). No statistical differences between T0 and T1 were observed.

Variables	T0 (*N* = 200)	T1 (*N* = 172)
Italian Nationality (%)	98%	98.3%
Marital status (%)	Unmarried: 13.1% Married/cohabitant: 66.8% Separated/Divorced: 13.1% Widow: 7%	Unmarried: 14% Married/cohabitant: 66.1% Separated/Divorced: 12.9% Widow: 7%
Educational status (%)	Nothing: 1% Primary school: 13.6% Middle school degree: 21.6% High school degree: 47.7% Academic degree: 15.6% Post-academic degree: 0.5%	Nothing: 1.2% Primary school: 12.9% Middle school degree: 19.9% High school degree: 49.1% Academic degree: 16.4% Post-academic degree: 0.6%
Smoking (%)	12.1%	12.3%
Physical activity Index (%)	Inactive: 42.5% Moderately inactive: 16.5% Moderately active: 19.5% Active: 21.5%	Inactive: 48.2% Moderately inactive: 14.1% Moderately active: 15.9% Active: 21.8%

At T0 evaluation, 93.5% of the women were in menopause, 17.5% had bone fragility fractures, and 73.5% supplemented with vitamin D. Moreover, mean weight was 60.9 ± 10.8 kg and mean BMI was 23.5 ± 3.8, which meant normal weight. Waist circumference was 92.1 ± 11.4 cm, Fat Mass was 26.7 ± 7.0%, Fat Free Mass was 72.9 ± 7.4% and Total Body Water was 53.7 ± 4.9%.

At T1 evaluation, mean weight was 60.3 ± 10.4 kg and mean BMI was 23.73 ± 3.9, which meant normal weight. Waist circumference was 91.24 ± 11.07 cm, Fat Mass was 27.2 ± 6.7%, Fat Free Mass was 72.8 ± 6.7% and Total Body Water was 53.3 ± 5.0%. Both results were comparable.

The MD adherence questionnaire showed that both at T0 and T1 a majority of the women had a medium MD adherence level (Figure 2). A chi-square analysis showed a significant statistical difference in the degrees of MD adherence both at T0 ($\chi_2{}^2 = 128.29$, $p < 0.001$) and T1 ($\chi_2{}^2 = 137.39$, $p < 0.001$).

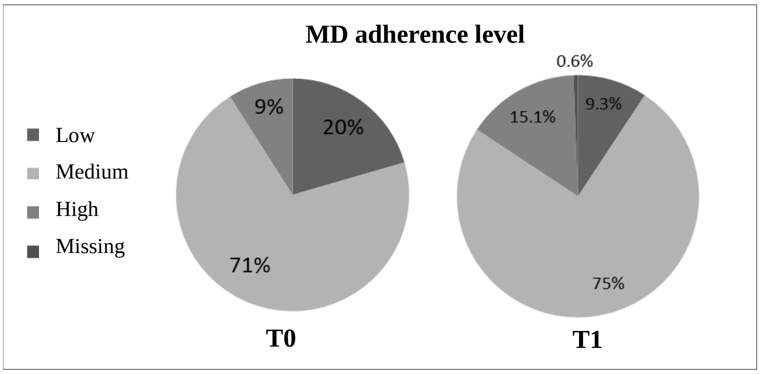

Figure 2. MD adherence level of peri- and post-menopausal women, at T0 ($N = 200$) and T1 ($N = 171$).

Mean score of MD adherence at T0 and T1 was respectively 6.98 ± 1.74 and 7.53 ± 1.68. Paired sample t-test revealed a statistically significant difference between T0 and T1 ($p < 0.001$), so MD score increased (Figure 3). In particular, the consumption of vegetables and nuts significantly increased (respectively, $p = 0.003$ and $p = 0.037$), and daily consumption of red and processed meat decreased ($p = 0.004$). Also, the consumption of calcium rich mineral water increased significantly ($p < 0.001$).

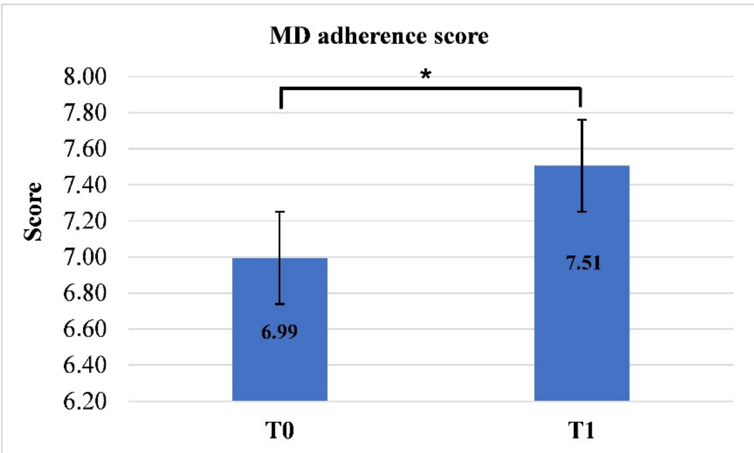

Figure 3. MD adherence score at T0 ($N = 200$) and T1 ($N = 171$) (Paired sample t-test; * $p < 0.001$).

The mean value of daily calcium intake was 866.2 ± 301.9 mg at T0 and 907.8 ± 304.8 mg at T1. At T0 and T1, participants were classified into adequate and inadequate groups (calcium intake higher than PRI for the Italian menopausal population or not) and then we assed statistical differences by means of chi-square analysis. The majority of participants had an inadequate calcium intake both at T0 ($\chi_2{}^2 = 102.24$, $p < 0.001$) and T1 ($\chi_2{}^2 = 76.00$, $p < 0.001$).

Figure 4 shows the dietary calcium intake as function of MD adherence level at T0 and T1 (it should be noted that taking into account other measures -such as demographic variables- the same trend was observed). No statistically significant differences were observed. Mean values (and standard deviations) at T0 were 839 ± 295, 870 ± 311, 900 ± 250 for low, medium, and high MD adherence, respectively. At T1, mean values (and standard deviations) were 914 ± 345 for low adherence, 885 ± 284 for medium adherence, and 1011 ± 368 for high adherence, showing an increase in calcium intake for high MD adherence from a descriptive point of view.

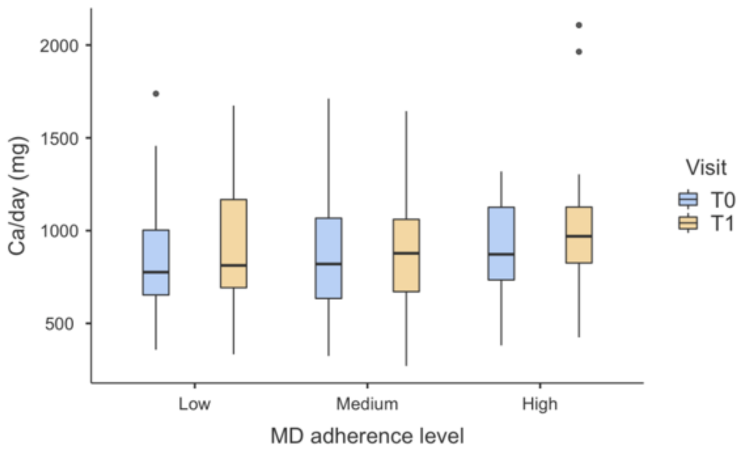

Figure 4. Box-plots chart showing dietary calcium intake in the three degrees of MD adherence, at T0 and T1. No statistically significant differences were observed. Outliers are represented by dots.

4. Discussion and Conclusions

The role of nutrition on bone health, especially the Mediterranean diet, has been widely discussed as it pertains to women during pre- and post-menopause [38,39]. Although a cause-effect relationship between MD and BMD and/or fragility fractures risk has not emerged, much evidence has proven the importance of a Mediterranean diet for bone health, encouraging the consumption of vegetables, fruits, nuts, and fish, rather than red and processed meats, sweet beverages, and high-energy density food [25,40].

Our study described the association between MD and dietary calcium intake in a population of two hundred peri- and post-menopausal women. Moreover, it highlighted the importance of preventive action (such as a 15–20 min nutritional conversation according to good clinical practice) to improve lifestyle habits and delay the consequences of osteoporosis.

This population showed a medium MD adherence level both at T0 (70.5%) and T1 (75%). The score increased significantly (6.98 ± 1.74 vs. 7.53 ± 1.68, $p < 0.001$), and could be suggestive of an amelioration of dietary habits. Dietary screening and nutritional intervention have often been useful for the management of chronic conditions, such as obesity and diabetes, and to improve lifestyle [41–43]. In this population, the consumption of healthy food groups also increased, such as vegetables ($p = 0.003$) and nuts ($p = 0.037$), and the consumption of red and processed meats decreased simultaneously ($p = 0.004$).

The majority of participants had an inadequate calcium intake both at T0 (866.2 ± 301.9 mg) and T1(907.8 ± 304.8 mg) respect to PRI for the Italian menopausal population (1200 mg per day). Our data are in line with Italian surveys on nutrients intake. To our knowledge, mean daily calcium intake in the Italian diet varies from 738 to 829 mg/day. The most recent Italian survey on food consumption was developed by INRAN (Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione-Italian Research Institute for Foods and Nutrition) during 2005–2006 [15,44,45]. In the adult population 18–65 years of age, calcium intake was about 800 mg/day for men and 730 mg/day for women, and 825 and 754 mg/day for men and women aged more than 65 years, respectively [15]. Other recent surveys reported data for specific disease groups, such as patients with inflammatory bowel disease [46], or adults with Type 1 Diabetes [47], or in regional populations. Castiglione et al. randomly collected data in a sample of 1838 subjects in the city of Catania, southern Italy, and reported that mean daily calcium intake among women was 798.23 mg, and 778.4 mg/for women aged more than 70 years [44].

It is interesting to highlight the consumption of calcium-rich mineral water increased significantly ($p < 0.001$) from T0 to T1. Although milk and dairy products give the greatest contribution, providing up to 80% of the total daily intake of calcium [44,45], natural mineral water with a calcium content ≥ 150 mg/L [48] may contribute to daily calcium requirements and has been demonstrated to be a good source of bioavailable calcium [49].

The positive contribution of the MD on bone health and osteoporosis prevention has been widely studied [24,40]. A recent systematic review on observational studies by Kunutsor et al. reported that limited evidence is available to demonstrate the beneficial effects of the MD on hip fractures [25]. Nevertheless, current literature has revealed that the consumption of some typical Mediterranean food groups (i.e., vegetables, fruits, nuts, low-fat dairy products, fish) is fundamental for the maintenance of a good bone health [27–30].

Our data show that, although not statistically significant, both at T0 and T1 a slight increase in calcium intake was observed for high adherence to MD diet from a descriptive point of view. Not only is the MD rich in plant origin foods, low-fat milk and dairy products, and fish, but the adherence to a healthier lifestyle may also sensitize populations to balanced dietary choices, which contribute to adequate daily nutrients intake [50].

This prospective study has some limitations: first, it is a correlational study, so a cause-effect relationship between MD adherence and calcium intake could not be established. A randomized controlled trial would be useful to deepen this theme. Moreover, in the study is not present a control group, that did not receive a nutrition conversation. This could have been useful to assess the effect of a short nutrition dialogue (15–20 min) on dietary habits change.

Finally, it should be noted that in our population a significant relation between MD and bone metabolism was not observed. Nevertheless, literature review and exploratory data suggest that MD could represent a sustainable and useful dietary pattern to ameliorate calcium intake. Further research is needed to prove hypothesized correlation and to acquire new data in order to apply it as a therapeutic adjunct to medication.

In conclusion, greater attention should be given to the diet as a complex of bioactive compounds and nutrients, and their interactive effects. In this context, the MD has emerged as the best choice to prevent many chronic diseases. An optimal calcium intake, according to the recommended daily allowance, and a dietary pattern in the Mediterranean style have proven their efficacy in preventing osteoporosis and maintaining good bone health.

The results in this population of peri- and post-menopausal women, show that a higher daily calcium intake is recorded in higher levels of MD adherence. In addition, a short duration (no more than 20 min) nutritional interview, during which advice was provided in the context of a good clinical practice routine, was sufficient to obtain promising results in terms of lifestyle improvement and prevention of osteoporosis.

Author Contributions: M.L.B. conceived the study; B.P. and S.Q. designed the study; S.Q. performed the intervention; S.Q. and B.P. and G.G. analyzed the data; F.G. contributed to preparing the materials and the analysis tools; B.P., S.Q., G.G. and M.L.B. wrote the paper. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of "Comitato Etico Area Vasta Centro, Azienda Ospedaliera Universitaria Careggi", Florence, Italy (protocol code number 11097_oss, 25/07/2017).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

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Conflicts of Interest: B.P., S.Q., G.G., F.G.: None. M.L.B. has received honoraria from Amgen, Bruno Farmaceutici, Calcilytix, Kyowa Kirin; Academic grants and/or speaker: Abiogen, Alexion, Amgen, Bruno Farmaceutici, Echolight, Eli Lilly, Kyowa Kirin, MSD, NPS, Servier, Shire, SPA, Theramex; Consultant: Alexion, Bruno Farmaceutici, Kyowa Kirin, Servier, Shire.

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Mediterranean Diet and Physical Activity Nudges versus Usual Care in Women with Rheumatoid Arthritis: Results from the MADEIRA Randomized Controlled Trial

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Abstract: In rheumatoid arthritis (RA), diet quality and nutritional status have been shown to impact the disease activity and adherence to the Mediterranean diet (MD) has been suggested as an anti-inflammatory regime to improve disease status and reduce cardiovascular risk. The Mediterranean DiEt In Rheumatoid Arthritis (MADEIRA) was a single-blind (statistician), two-arm randomized clinical trial, investigating the effects of a 12-week lifestyle intervention, including a personalized isocaloric MD plan with the promotion of physical activity (PA), supported through a clinical decision support systems (CDSS) platform, versus usual care in women with RA. Forty adult women with RA on remission were randomly allocated (1:1 ratio) to either the intervention or the control arm. The intervention group received personalized MD plans and lifestyle consultation on improving PA levels, whereas the controls were given generic dietary and PA advice, based on the National Dietary Guidelines. The primary outcome was that the difference in the MD adherence and secondary outcomes included change in disease activity (DAS28), anthropometric indices (BodPod), dietary intake, PA, vitamin D concentrations, and blood lipid profiles after 12 weeks from the initiation of the trial. At 3 months post-baseline, participants in the MD arm exhibited greater adherence to the MD compared with the controls ($p < 0.001$), lower DAS28 ($p < 0.001$), favorable improvements in dietary intake ($p = 0.001$), PA ($p = 0.002$), body weight and body composition ($p < 0.001$), blood glucose ($p = 0.005$), and serum 1,25(OH)$_2$D concentrations ($p < 0.001$). The delivery of the MD and PA promotion through CDSS nudges in women with RA in an intensive manner improves the MD adherence and is associated with beneficial results regarding disease activity and cardiometabolic-related outcomes, compared with the usual care.

Keywords: lifestyle medicine; immunonutrition; patient involvement; nutritional status; medical nutrition therapy; rheumatic disease; obesity; anti-inflammatory diet; 25(OH)D

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1. Introduction

Rheumatoid arthritis (RA) is one of the most common autoimmune diseases, inducing a systematic inflammatory state of the joints, gradually leading to bone resorption and cartilage erosion and the destruction of the affected joints [1,2]. Major symptoms include swelling of the joints, stiffness and pain, which negatively affect patients' quality of life (QoL) [3]. Recent estimates of the prevalence of RA suggest a 1–2% global prevalence, with approximately two to three times more women being affected compared to the men [4,5]. In general, female patients tend to demonstrate worse outcomes than males. The treatment of RA aims in improving symptomatology, and reducing complications and lowering disease activity, allowing for the induction and sustainment of disease remission [3,6].

A plethora of genetic and environmental factors have been implicated in the pathogenesis of RA, with diet quality playing a significant role in the development of the entity, its pathophysiology, the manifestation of symptoms, and the management of RA [7–9]. Various dietary patterns, including the Mediterranean diet (MD), and individual nutrients including certain types of fatty acids and vitamin D, have been investigated for their potential associations with the development and prognosis of RA [10–14]. Dietary factors may interfere with several inflammatory pathways, influencing key pathophysiology features in RA [15]. For instance, a high-fat Western-type diet based on animal origin foods, which induces excess body weight and body fat, has been positively associated with the early onset of RA and a burdensome disease state [16,17]. A putative mechanism is the potential crosstalk between chronic obesity and RA inflammation, resulting in the upregulation of pro-inflammatory mediators, such as the tumor necrosis factor-α (TNF-α), interleukin-6 (IL-6), and C-reactive protein (CRP) [18]. Furthermore, Western-type diets decrease the odds of achieving and sustaining disease remission, inducing greater disease activity scores [19].

The MD is a predominantly plant-based diet that includes a variety of fruits, vegetables, whole grains, seeds, legumes, olive oils, and fish, characterized by a moderate intake of dairy products and a low consumption of animal fats [20]. Adherence to the MD and its individual components entails a variety of anti-inflammatory effects, alleviating RA symptomatology [10,11,21–23]. In parallel, the MD has been shown to exert protective and beneficial effects against obesity and cardiovascular (CV) and metabolic disorders [24–26].

The risk for the development of cardiovascular diseases (CVD) is markedly increased in RA as a result of the chronic inflammation in various body systems, including the heart and the vascular system [27,28]. In particular, the risk of developing heart failure is double in RA compared with the unaffected population, with patients demonstrating a preserved ejection fraction >50%, without necessarily any clinical evidence of coronary artery disease (CAD) [28]. For this, the European League Against Rheumatism (EULAR) recommends the multiplication of traditional cumulative CV risk scores in RA by ×1.5 in order to reflect the increased CVD risk associated with RA. In RA, accumulative CV risk factors are associated with poorer outcomes [29] and reduced survival [30]. Recently, the EULAR recommended lifestyle modifications, including adherence to MD, regular exercise and smoking cessation, as protective measures against the development and progression of CVD [31].

With both RA and CVD being predominantly a "female challenge" [4,5], the need to address the efficacy of lifestyle modifications, including the MD in women with RA, becomes urgent. In this manner, the present randomized controlled trial (RCT) aimed to evaluate the effect of a personalized MD plan delivered through a clinical decisions support system (CDSS) platform versus usual care, in women with an RA diagnosis.

2. Materials and Methods

2.1. Study Design and Protocol

The Mediterranean DiEt In Rheumatoid Arthritis (MADEIRA) was a single-blind (statistician), two-arm randomized controlled trial, investigating the effects of a 12-week personalized lifestyle intervention including MD and PA promotion, versus usual care in women with RA. The study's protocol was registered at the Center for Open Science Framework (OSF, https://www.shorturl.at/krW24, accessed on 22 January 2023). The reporting of the study follows the consolidated standards of reporting trials (CONSORT) statement [32].

2.2. Ethical Clearance

The Ethics Committee of Iaso Hospital (Athens, Greece) reviewed and approved the protocol of the study (Approval Code #d310519). All principles of the Helsinki Declaration and its later amendments were adhered to, and the terms of Good Clinical Practice were applied. Informed consent was obtained from all subjects involved in the study.

2.3. Participants

Adult women with a definite RA diagnosis based on the American College of Rheumatology (ACR)/EULAR 2010 classification criteria [33] were recruited from the outpatient clinic of Iaso Hospital (Athens, Greece) during 2021–2. Information on the study aim, protocol, and methodology were provided to all patients through a detailed leaflet before recruitment. Patients were advised to read the leaflet in detail and sign the informed consent in two copies, keeping one. The study took place from November 2021 until April 2022, at Iaso Hospital, in Athens. The inclusion and exclusion criteria for participation in the study are detailed in Table 1.

Table 1. Inclusion and exclusion criteria for participation in the study.

Inclusion Criteria	Exclusion Criteria
(1) Adult women ($\geq$ 18 years of age) with an RA diagnosis according to the ACR/EULAR criteria [33] for >2 years (2) With mild-moderate disease activity based on the DAS28 (DAS28 < 3.2) (3) On an unchanged treatment regime for >6 months (4) Who provided consent for participation	(1) Adolescent women (2) Patients with altered treatment regime $\leq$ 6 months before, or during the trial (3) Women with RA with active disease (DAS28 > 5.1) [34] (4) People unable to read and comprehend the consent form (5) Patients with psychiatric conditions (6) Pregnant or lactating women (7) Women on weight loss medication (8) Women following a vegan diet $\leq$ 5 years prior to screening (9) Those who did not consent or were unable to provide consent (10) Women with allergies, food intolerances, serious or life-threating illness, e.g., malignancy; infections; heart, liver, or renal failure; congenital metabolic diseases; malabsorption; or cognitive disorders (11) Alcoholism or drug addiction (12) Women taking vitamin or mineral supplementation during or $\leq$6 months prior to screening

ACR—American College of Rheumatology; DAS28—disease activity score 28 [34]; EULAR—European League Against Rheumatism; RA—rheumatoid arthritis.

2.4. Randomization Procedure

Patients were randomly allocated to the intervention or the control arm, on blocks of 1, using an online random allocation software (https://stattrek.com/, accessed on 28 January 2023). Investigators and patients were aware of the allocation. An independent researcher was responsible for the randomization. The statistician was blinded to the allocation (single blind).

2.5. Procedures and Tools

2.5.1. Medical History and RA Specificities

A detailed medical history that included general information and disease-specific data (disease activity, symptoms, complications, treatment) was obtained by the attending rheumatologist specialist.

All women underwent clinical evaluation of RA through an objective physical articular examination, which was also used to calculate the Disease Activity Score of 28 joints (DAS28) [34] by the rheumatologist. The DAS28 combines data regarding the number of swollen and tender joints (based on 28 joints in total), perceived general health, and the acute phase response to the disease [34]. The score ranges between 0 to 9.4, with values exceeding 5.1 being indicative of an active disease and scores < 3.2 pointing to an inactive, well-controlled disease status [34].

2.5.2. Dietary Intake and MD Adherence

A semi-quantitative Food Frequency Questionnaire (FFQ), previously validated in Greek patients with CVD, was employed for the assessment of the usual dietary intake of participants [35]. Portion sizes estimations were facilitated with the demonstration of food replicas and real-size food photos.

The Diet Analysis Plus (version 6.1, Wadsworth 2003) software was used to analyze individual FFQs and previous day 24 h diet recalls (treatment adherence). The daily dietary intake of saturated fatty acids (SFA), monounsaturated fatty acids (MUFA), total fat, dietary fiber, and vitamin D were calculated for each participant.

Adherence to the MD was assessed using the Mediterranean Diet Score (MedDietScore) [36]. The score is based on the reported frequency of consumption of 11 food groups, which are either representative, or not, of the MD pattern [36]. The total score is calculated by summing the scores of each individual food group and ranges between 0–55 in a linear manner, with greater scores being indicative of increased adherence to the MD and a lower risk for the development of CVD [36].

2.5.3. Physical Activity (PA) Levels

The Greek version of the International Physical Activity Questionnaire (IPAQ) [37,38] for young and middle-aged adults was completed by all participants. The IPAQ measures health-related physical activity (PA) [38]. The IPAQ consists of 5 domains, each recording distinct activities, including (i) work-related PA; (ii) transportation PA; (iii) housework, house maintenance and caring for the family PA; (iv) recreation, sport and leisure PA; and (v) time spent sitting. The PA levels of each participant were expressed as metabolic equivalents of task (METs), in min per week.

2.5.4. Anthropometric Indices

Body weight (BW) was measured in kg, to the nearest g, using the Air Displacement Plethysmography method (Bodpod® Body Composition Tracking Systems, Life Measurement, Inc., Rome, Italy). Fat mass (FM) and fat-free mass (FFM) of participants were also estimated using the same device. For the Bodpod tests, participants did not perform any exercise or consume any foods and drinks for at least 2 h prior to the assessment, and were dressed in their underwear only [39], according to manufacturer guidelines.

Height was measured with a calibrated stadiometer to the nearest 0.1 cm (Seca 217, Seca, Hamburg, Germany).

Body mass index (BMI) of each participant was calculated as the ratio of BW (kg) to the square of height (m^2). The BMI cutoffs for the classification of underweight (< 18.5 kg/m^2), overweight (25 kg/$m^2 \leq$ BMI < 30 kg/m^2), and obesity (BMI ≥ 30 kg/m^2) suggested by the World Health Organization (WHO) were applied [40] for the assessment of the BW status of participants.

2.5.5. Blood Samples: Collection and Assays

Each patient provided morning whole blood samples (20 mL) for the isolation of the serum and plasma after an overnight fast. Ethylenediamine tetra-acetic acid (EDTA) was used for the plasma isolation. For the isolation of serum, whole blood was previously allowed to clot at room temperature for 20 min. Whole blood samples were centrifuged at 3000 rpm for 10 min at 4 °C. For all assays, freshly drawn blood samples were used.

Serum glucose (Glu), total cholesterol (TC), high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides (TG), and CRP were quantified with an automatic biochemical analyser using manufacturer's reagents (Cobas 8000 modular analyser, Roche Diagnostics GmbH, Mannheim, Germany).

An automated chemiluminescence system (Cobase 801 analytical module, Roche Diagnostics GmbH, Mannheim, Germany) was used to determine the concentrations of 1,25-dihydroxyvitamin D [1,25$(OH)_2$D] in the serum of the participants, using manufacturer's reagents.

2.6. Intervention and Comparator

2.6.1. Intervention

In the intervention arm, isocaloric personalized dietary plans according to the principles of the MD, patients' energy expenditure requirements (EER), and food preferences were provided to the participants. In parallel, advice was also provided on increasing the PA levels according to the EULAR recommendations [31].

A CDSS platform was used for the delivery of the patient education, as previously detailed [41,42]. The specific CDSS was developed during 2016 and has been used in clinical practice as a complementary tool for the hospital's dieticians and as a patient nudge tool [41,43]. CDSS platforms are employed to improve the delivery of healthcare interventions by facilitating medical decisions through the provision of targeted knowledge and health information [44]. Personalized login usernames and passwords were administered to all participating patients in the intervention arm, in order to have access to their personal CDSS database account, by which they could track their progress regarding BW, healthy eating, and PA levels.

The intervention lasted for a total of 12 weeks. During this time, two experienced registered dietitians (RDNs) communicated with participants on a biweekly basis through telephone calls to catch up, resolve possible queries, and provide support (A.G. and E.D.)

2.6.2. Comparator (Control Arm)

Participants in the control arm did not receive a personalized MD plan, nor did they have access to the CDSS platform. In contrast, they were given generic dietary advice and PA recommendations that were in line with the Greek National Dietary Guidelines for adults [45].

2.6.3. Treatment Adherence

According to the RDN's instructions, all patients kept self-filled weekly food diaries that were evaluated remotely through CDSS (intervention group) or emails (control group). Unexpected phone calls were also made to participants to obtain 24 h diet recalls.

2.6.4. Study Timepoints

All measurements were performed at the baseline and at the end of the intervention period, at 12 weeks.

2.7. Primary and Secondary Outcomes

The primary outcome of the study was the difference (Δ) in the degree of adherence to the MD, assessed through the MedDietScore.

Secondary outcomes included differences (Δ) in disease activity (DAS28), dietary intake (SFA, MUFA, total fat, dietary fiber), as well as CV risk factors and inflammatory markers (BMI, FM, FFM, TC, HDL, LDL, TG, CRP levels), total PA levels, and 1,25(OH)$_2$D concentrations.

2.8. Sample Size Calculation

A minimum sample size of 34 patients (17 per group) was deemed sufficient to result in a clinically important difference of 3.0 in the MedDietScore [standard deviation of mean (SD) = 3] using a two-tailed *t*-test with 80% power and a 5% level of significance (α).

2.9. Statistical Analyses

The Kolmogorov–Smirnov test was used to assess the normality of the distribution. Descriptive statistics were calculated for all parameters. Continuous data were expressed as mean $\pm$ standard deviation (SD), and dichotomous variables as counts (*n*) and proportions (%).

Differences between the two arms were assessed using Student's *t*-test for normally distributed variables or the Mann–Whitney U test for those not normally distributed. For investigating possible intra-group differences, a paired samples *t*-test or the Wilcoxon test was applied. Correlations between the MedDietScore and dietary, anthropometric, and biochemical parameters were assessed using either the Pearson's or the Spearman correlation coefficients for normally distributed and not normally distributed variables, respectively. All correlations were assessed at the end of treatment.

Statistical significance was set at p-value < 0.05. All analyses were performed with the Statistical Package for the Social Sciences (SPSS) (version 21.0, SPSS, Inc, IBM, Chicago, IL, USA) and the Jamovi project (version 1.2.27.0) [46].

3. Results

3.1. Participants

The study sample comprised 40 women with RA meeting the inclusion criteria. All participants completed the trial and were incorporated in the final analyses, without any dropouts or patients lost-to-follow-up being recorded. The CONSORT diagram [32] of the study's procedure is presented in Figure 1. All women inhabited the Attica region in Greece, were non-smokers, and reported consuming alcohol rarely or abstaining from alcohol.

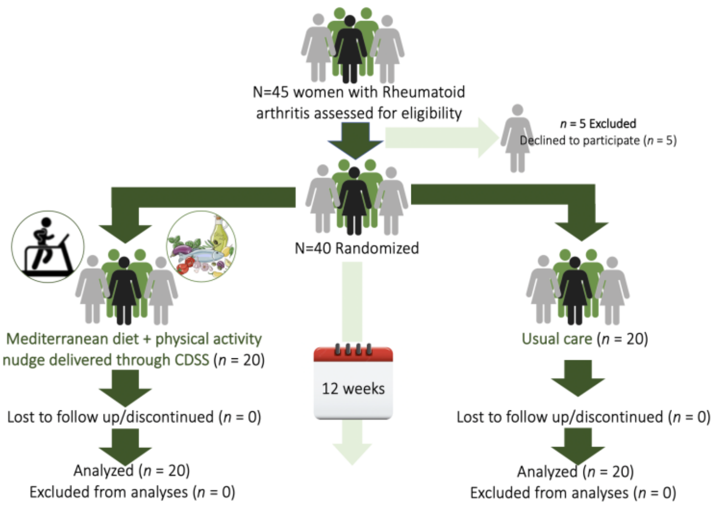

Figure 1. CONSORT [32] diagram of the study's procedures.

Table 2 details the characteristics of the participants at the baseline. No differences were observed between the intervention and the control arm at the baseline regarding the participant age, anthropometric indices, body composition, dietary intake, blood markers, disease activity score, PA METs, and MedDietScore.

Table 2. Characteristics of the participating women at baseline *.

Characteristics		Enrolled (N = 40)	Intervention Arm (n = 20)	Control Arm (n = 20)
	Age (years)	34.03 ± 5.45	34.15 ± 5.95	33.9 ± 5.06
Anthropometry:	BW (kg)	78.86 ± 19.46	79.19 ± 21.38	78.52 ± 17.88
	BMI (kg/m^2)	25.76 ± 5.22	26.13 ± 5.89	25.40 ± 4.59
	FM (% of BW)	21.13 ± 12.07	20.63 ± 11.86	21.64 ± 12.56
	FFM (% of BW)	57.68 ± 11.92	57.53 ± 13.33	57.82 ± 10.66
Weight status:	Normoweight/Overweight/Obese (n)	22/14/4	12/6/2	10/8/2
Blood assays:	Glucose (mg/dL)	108.13 ± 17.16	110.61 ± 7.34	105.65 ± 23.19
	TC (mg/dL)	213.21 ± 50.11	209.22 ± 53.02	217.2 ± 48.07
	HDL (mg/dL)	69.33 ± 21.16	71.78 ± 17.62	66.88 ± 24.42
	LDL (mg/dL)	129.20 ± 42.31	130.02 ± 45.87	128.37 ± 39.61
	TG (mg/dL)	113.34 ± 67.12	112.23 ± 75.76	114.45 ± 59.20
	CRP (mg/dL)	0.74 ± 0.12	0.71 ± 0.11	0.77 ± 0.12
	1,25(OH)2D (ng/mL)	32.97 ± 4.10	33.79 ± 3.94	32.14 ± 4.19
Physical activity (IPAQ):	METs-min/week	647.46 ± 308.01	580.78 ± 322.39	714.14 ± 284.24
Adherence to the MD:	MedDietScore	38.25 ± 3.21	38.36 ± 3.46	38.14 ± 3.03
Daily dietary intake:	Total fat (g)	68.76 ± 9.49	67.02 ± 7.15	70.50 ± 11.29
	Dietary cholesterol (mg)	199.19 ± 45.49	188.94 ± 58.45	209.44 ± 24.70

Table 2. *Cont.*

Characteristics		Enrolled (N = 40)	Intervention Arm (n = 20)	Control Arm (n = 20)
	Fiber (g)	21.24 ± 4.85	19.98± 4.28	17.95 ± 4.24
	SFA (g)	18.98± 3.64	19.87 ± 2.16	18.09 ± 4.58
	MUFA (g)	29.63 ± 5.85	30.84 ± 5.47	28.42 ± 6.11
Disease activity:	DAS28	2.82 ± 0.19	2.83 ± 0.19	2.81 ± 0.20

1,25(OH)2D—1,25-Dihydroxyvitamin D; BW—body weight; BMI—body mass index; CRP—C-reactive protein; DAS28—disease activity score 28 joints [34]; FFM—fat-free mass; FM—fat mass; HDL—high-density lipoprotein; IPAQ—International Physical Activity Questionnaire [37]; LDL—low-density lipoprotein; MD—Mediterranean diet; MedDietScore—Mediterranean Diet Score [36]; MET—metabolic equivalents of task; MUFA—mono-unsaturated fatty acids; NS—not significant; SFA—saturated fatty acids; TC—total cholesterol; TG—triglycerides; * Data are expressed as counts (n) or mean values ± standard deviation of mean (SD).

3.2. Mediterranean Diet Adherence and Dietary Intake

Table 3 presents the characteristics of the participants in each arm and pre-post intervention comparisons. Post-intervention, a significant increment was observed in the MD adherence among the participants in the intervention arm ($p < 0.001$), with a mean statistically significant increase of 3.75 units, while no change was observed among participants allocated to the control arm.

3.3. Disease Activity

DAS28 was significantly reduced at 3 months compared to the baseline among patients who received the intensive lifestyle intervention ($p < 0.001$). DAS28 correlated positively with the BMI (r = 0.330, $p = 0.038$) and dietary fat intake (r = 0.476, $p = 0.002$), and negatively with the MedDietScore (r = −0.452, $p = 0.003$).

3.4. Anthropometrics and PA Levels

At 12 weeks post-baseline, patients allocated in the intervention group exhibited a greater reduction in BW, BMI, and FM ($p < 0.001$) compared with the controls. PA levels were also improved in the intervention arm compared to the controls after 3 months ($p = 0.002$).

Table 3. Characteristics of the participating women at baseline and end of treatment (12 weeks) *.

Characteristics		Intervention Arm (n = 20)		p-Values within Timepoints †	Control Arm (n = 20)		p-Values within Timepoints †	p-Values between Groups †		p-Values between Groups †
		before	after		before	after		Baseline	12 Weeks	Δ
Anthropometry:	BW (kg)	79.2 ± 21.4	77.1 ± 20.8	<0.001	78.5 ± 17.9	80.6 ± 18.3	<0.001	0.916	0.576	<0.001
	BMI (kg/m^2)	26.13 ± 5.89	25.42 ± 5.63	<0.001	25.40 ± 4.59	26.04 ± 4.58	<0.001	0.663	0.702	<0.001
	FM (% of BW)	20.6 ± 11.9	20.3 ± 12.1	<0.001	21.6 ± 12.6	22.1 ± 12.1	0.002	0.794	0.665	<0.001
	FFM (% of BW)	57.5 ± 13.3	56.7 ± 13.3	0.001	57.8 ± 10.7	57.8 ± 11.1	0.954	0.940	0.774	0.348
Blood assays:	Glucose (mg/dL)	110.6 ± 7.3	104.8 ± 5.3	<0.001	105.7 ± 23.2	104.7 ± 23.2	0.401	0.368	0.964	0.005
	TC (mg/dL)	209.2 ± 53.0	200.6 ± 56.5	0.183	217.2 ± 48.1	228.8 ± 53.0	0.209	0.621	0.111	0.071
	HDL (mg/dL)	71.8 ± 17.6	69.7 ± 19.2	0.680	66.9 ± 24.4	73.4 ± 27.3	0.133	0.472	0.625	0.193
	LDL (mg/dL)	130.0 ± 45.9	126.5 ± 52.0	0.637	128.4 ± 39.6	132.3 ± 45.3	0.623	0.904	0.708	0.493
	TG (mg/dL)	112.2 ± 75.8	97.5 ± 57.7	0.057	114.5 ± 59.2	126.3 ± 83.6	0.380	0.918	0.212	0.086
	CRP (mg/dL)	0.71 ± 0.11	0.72 ± 0.11	0.408	0.77 ± 0.12	0.75 ± 0.11	0.367	0.084	0.460	0.240
	1,25(OH)$_2$D (ng/mL)	33.8 ± 3.9	51.6 ± 11.8	<0.001	32.1 ± 4.2	40.4 ± 6.4	<0.001	0.208	<0.001	0.001
Physical activity (IPAQ):	METs (min/week)	580.8 ± 322.4	616.5 ± 315.9	0.002	714.1 ± 284.2	684.7 ± 251.1	0.065	0.174	0.454	0.002
MD adherence:	MedDietScore	38.36 ± 3.46	42.11 ± 2.48	<0.001	38.14 ± 3.03	38.36 ± 2.74	0.359	0.829	<0.001	<0.001
Daily dietary intake:	Total fat (g)	67.02 ± 7.15	61.19 ± 7.90	<0.001	70.50 ± 11.29	73.42 ± 11.57	<0.001	0.251	<0.001	<0.001
	Cholesterol (mg)	188.9 ± 58.5	169.2 ± 50.3	<0.001	209.4 ± 24.7	224.6 ± 28.3	<0.001	0.157	<0.001	<0.001
	Fiber (g)	19.98 ± 4.28	26.09 ± 5.00	<0.001	17.95 ± 4.24	23.73 ± 4.24	0.067	0.140	0.116	<0.001
	SFA (g)	19.87 ± 2.16	16.73 ± 3.12	0.004	18.09 ± 4.58	18.48 ± 4.77	0.132	0.125	0.177	0.001
	MUFA (g)	30.84 ± 5.47	36.98 ± 5.82	<0.001	28.42 ± 6.11	28.73 ± 5.38	0.433	0.195	<0.001	<0.001
Disease activity:	DAS28	2.83 ± 0.19	2.71 ± 0.14	<0.001	2.81 ± 0.20	2.80 ± 0.17	0.804	0.744	0.054	<0.001

1,25(OH)2D—1,25-Dihydroxyvitamin D; Δ—change from baseline to end of treatment; BW—body weight; BMI—body mass index; CRP—C-reactive protein; DAS28—disease activity score 28 joints [34]; FFM—fat-free mass; FM—fat mass; HDL—high-density lipoprotein; IPAQ—International Physical Activity Questionnaire [37]; LDL—low-density lipoprotein; MD—Mediterranean diet; MedDietScore—Mediterranean Diet Score [36]; MET—metabolic equivalents of task; MUFA—mono-unsaturated fatty acids; NS—not significant; SFA—saturated fatty acids; TC—total cholesterol; TG—triglycerides. * Data are expressed as mean values ± standard deviation of mean (SD); † p-value: significant differences between the control and the intervention group at baseline analyzed by independent sample t-test or the Mann–Whitney U test, where applicable.

3.5. Dietary Intake

The post-intervention dietary intake of total fat, dietary cholesterol, and SFA were significantly lower in the intervention arm compared with the controls, while the consumption of MUFA and fiber were higher in the first compared with the latter ($p \leq 0.001$). The MedDietScore correlated positively with the MUFA (r = 0.315, $p = 0.047$) and fiber intake (r = 0.477, $p = 0.02$), and negatively with the consumption of total fat (r = −0471, $p = 0.002$) and dietary cholesterol (r = −0.707, $p = 0.001$).

3.6. Blood Glucose, Serum Lipids, CRP and Vitamin D Concentrations

Both study groups exhibited greater serum vitamin D concentrations at 3 months after the initiation of the trial ($p = 0.001$), but, within the intervention arm, the mean increment was greater compared with that observed in the controls ($p < 0.001$). Serum vitamin D levels were negatively related to BW (r = −0.533, $p < 0.001$), FM as a percentage of BW (r = −0.363, $p = 0.021$), BMI (r = −0.560, $p < 0.001$), and the dietary intake of SFA (r = −0.348, $p = 0.028$). Vitamin D levels also correlated positively with the intake of MUFA (r = 0.436, $p = 0.005$) and dietary fiber (r = 0.510, $p = 0.001$).

No differences were noted with regard to the CRP and blood lipids levels between the intervention and comparator arms. On the other hand, blood glucose concentrations were improved among participants receiving the lifestyle intervention ($p = 0.005$).

Serum TG concentrations correlated negatively with the MedDietScore (r = −0.326, $p = 0.004$).

4. Discussion

The present study showed that a 12-week personalized MD plan, paired with PA promotion and delivered with the support of CDSS was successful in improving adherence to the MD, disease activity, PA levels, and a plethora of cardiometabolic outcomes among female patients with RA.

Adherence to the MD can be a useful tool to combat immune-mediated inflammatory diseases, including RA [23]. Results from other countries have shown a suboptimal adherence to the MD among patients with an RA diagnosis [47], with most patients adopting diets of poor quality in general, failing to meet the daily requirements for many nutrients [48–51]. A recent observational study conducted in Greece, suggested that female patients with RA demonstrated low-to-moderate adherence to the MD, with a mean MedDietScore equal to 29.55 [22]. In agreement with this, participants herein exhibited a mean baseline MedDietScore of 38.25, indicative of a moderate MD adherence and the adoption of a diet of mediocre quality. Among patients allocated to the intervention arm, adherence to the MD was further improved after 12 weeks of the intervention. In parallel, previous research has shown that adherence to the MD is associated with improved health perception regarding RA and general health [52]. Previous studies on the MD pattern have also shown improvements in the subjective measures of RA disease activity [28–30].

RCTs delivering traditional Cretan MD or other anti-inflammatory dietary interventions in patients with RA have revealed improvements regarding disease activity [53–55], whereas others suggested differences in the level of MD adherence between patients with low and high disease activity [22], suggesting that diet quality and composition might affect RA status. In the current trial, improvement in MD adherence was associated with ameliorated disease status, as evidenced by lower disease activity (DAS28 was negatively associated with MD adherence). This might have been the result of ameliorated dietary intake, with the observed improvements in the consumption of MUFA and fiber and the reduction in SFA intake being possible precipitating factors. The anti-inflammatory effects of MUFA in RA have been well-discussed in the context of the MD. In the TOMMOROW cohort [56], the dietary intake of MUFA was lower among patients with RA compared with healthy controls, while the ratio of the MUFA/SFA intake was positively associated with RA remission. The MD is considered as the ultimate anti-inflammatory dietary pattern, as it focuses on eating whole, plant-based foods that are rich in fiber and phytonutrients, while maintaining a stable glycemic response [57]. Dietary fiber is not digested in the small intestine, but upon fermentation by the colonic microflora, several microbial metabolites are produced that possess health-promoting effects. For instance, short chain fatty acids have been associated with improvements regarding microbial dysbiosis and the regulation of inflammatory biomarkers, such as plasma CRP, TNF-α, and IL-6, which are potent triggers of the RA disease activity [58]. There is evidence that a low-fiber dietary pattern may be linked to increased RA disease activity. For example, Elahi and associates showed that patients with RA on a low-fiber diet exhibited greater disease activity compared with those adhering to diets of higher-fiber contents [59].

In the present study, disease activity was also associated with BMI. The overall combined prevalence of overweight and obesity in the sample was high, namely 35% and 10%, respectively, and this observation is in accordance with previous studies indicating that excessive body weight is an important comorbidity in RA [22]. Patients with RA and comorbid obesity have been shown to exhibit greater DAS28 compared with the normoweight or overweight patients [60]. In RA, overweight and obesity consist of common results of long-term corticosteroid use and physical inactivity [61]. According to Padel, however [62], despite the seemingly worse disease activity, when imaging techniques are applied, patients with RA and obesity appear to have less inflammation and reduced rates of radiographic progression through time. A better diet quality in terms of adopting the MD pattern could be the possible route not only for managing RA symptoms, but also for maintaining a healthy BW and body composition [47]. Increased BW and body fat accumulation propels low-grade inflammation, thus, the adoption of the MD as an anti-inflammatory dietary pattern might induce a reduction in BW and tamper down inflammation. Herein, a 12-week MD intervention was effective at reducing BW, BMI, and FM among participants in the intervention arm compared with the controls.

RA, especially in the active disease state, is associated with considerable changes in blood lipids levels and insulin sensitivity, while metabolic changes, such as elevated TC, LDL, and TG concentrations, occur even in preclinical RA [63]. In the present study, TC, HDL, LDL, and TG remained unchanged in both study groups, but the TG levels were negatively associated with the MedDietScore, confirming the cardio-protective effects of the MD [24]. Additionally, the serum glucose levels were significantly lower among patients receiving personalized MD intervention compared with the controls, an observation that also implies the well-documented favorable effects of MD on glucoregulation [64].

There is evidence that the adoption of anti-inflammatory diets, including the MD, is negatively associated with inflammatory biomarkers in RA, such as CRP. In the randomized controlled study of Sköldstam and co-authors [53], patients with RA allocated to the MD arm exhibited significant reductions in CRP concentrations compared with the usual care group. Nevertheless, in the present study, CRP levels remained unchanged in both study arms, and this could be partially explained by the small sample size.

The role of vitamin D in immune-mediated inflammatory diseases, such as RA, has been extensively discussed in the literature. Vitamin D has been shown to exert immunomodulatory effects and downregulate pro-inflammatory agents [65]. Vitamin D deficiency is often observed in patients with RA [65,66], while hypovitaminosis is associated with the fastest disease progression, even in the early course of the disease [67]. A negative association between the serum vitamin D and RA disease activity has been reported, while vitamin D deficiency may be a potent contributor to CVD risk in RA [68]. In the present trial, 8 out of 40 patients with RA (20%) at the baseline had vitamin D insufficiency, with reference 1,25(OH)2D levels ranging between 20 to 68 ng/mL [69]. At the end of the trial, both study arms demonstrated a significant increase in the vitamin D serum levels, but the increment was sharper among participants in the intervention group than the control group at the end of the trial, with a mean concentration of 51.56 ng/mL vs. 40.36 ng/mL, respectively. The improvements noted in all study participants, irrespective of the treatment allocation, might be the result of the increased sunlight observed in the country during the summer months. Meta-analyses suggest that when vitamin D levels are improved (as in supplementation interventions), parallel improvements are also noted in the disease activity scores [66]. Thus, the ameliorated DAS28 observed at the end of the trial herein might well be the result of an overall improved vitamin D status.

Patients with RA tend to be inactive, in particular at the period following the diagnosis [70], with approximately 59% meeting the recommendations for PA [71]. In parallel, an RA diagnosis is reported as a persistent catalyst either for, or against, the performance of PA [72]. The use of nudges has been shown to increase PA levels and reduce sedentary behavior [73]. On the other hand, improvements in PA can also boost QoL and physical function [74], relieve pain, and increase aerobic capacity and CV fitness in RA [75,76]. In parallel, exercise is a known effector of circulating inflammatory markers [77] and an important contributor to cardiometabolic health [78]. In this manner, the improvements noted in the intervention arm herein might also be the result of greater PA among participants. In parallel, with improvements in PA and diet quality being parallel, it is also possible that they both consist of the result of nudging, or improved health-consciousness due to nudging.

Nudge policies aiming to modify health-related decisions, including dietary choices, are increasingly gaining popularity [79,80]. When nudge policies are delivered through CDSS platforms in particular, they can further improve the implementation of evidence [81]. According to a recent meta-analysis [82], a significant improvement in the proportion of patients receiving desired care is noted when CDSS are employed. Among patients with RA, previous studies have applied the CDSS for medication-related decisions [83] and for the incorporation of appropriate cultural contexts [84]. The present RCT consists of the first effort to use CDSS for improving lifestyle choices in RA.

Furthermore, the lifestyle intervention performed in the present RCT was carried out by experienced RDNs. Research has shown that when medical nutrition therapy (MNT) is applied by expert dietitians, patients tend to adhere to a greater degree and significant improvements are observed regarding their disease management [85–88]. In parallel, intensive lifestyle therapy, as performed herein, has also been shown to improve the health outcomes in comparison to standard care [85,89–91]. Furthermore, the use of CDSS for the delivery of interventions has been shown to improve clinical care [92]. Thus, it is possible that the additive effects of RDNs delivering the dietary intervention, the use of CDSS, and the more intensive meetings offered in the intervention arm may have corroborated for the observed improvements in the outcomes.

Patients with RA tend to underestimate the risk for developing CVD and are less concerned about the beneficial effects of protective lifestyle factors, such as the MD [93]. Therefore, personalized consultation sessions, as applied in the present trial, targeting improved MD adherence and higher levels of PA may have a beneficial impact not only with regard to the disease symptomatology, but also on the cardiometabolic and CV risk. There is evidence that increasing PA and/or exercise can simultaneously improve symptoms and reduce the impact of systemic RA manifestations [94]. A recent systematic review and meta-analysis revealed that the promotion of PA according to the public health recommendations improves CV fitness, muscle strength, and exercise behavior in patients with RA [76]. In the present trial, personalized lifestyle consultation sessions elevated the levels of PA of patients with RA at 12 weeks. Therefore, personalized nutrition and dietary guidance can promote diet quality and enhance disease management, serving as effective complementing treatment strategies for RA [95]. Such strategies can also enhance patient awareness on the value of lifestyle modification (healthy diet, regular exercise, smoking cessation, adequate sleep) on RA progression and remission. Based on the principles of the MD, Rondanelli and colleagues [96] have recently proposed a food pyramid adapted for patients with RA.

The small sample size and the possible bias that self-reported tools can cause comprise the limitations of the present study. For controlling these issues, a randomization protocol and validated questionnaires in Greek ample populations have been applied. In addition, the assigned RDNs were well experienced, and were able to detect unclear records and ask patients for proper clarifications.

5. Conclusions

In the present RCT, the delivery of a personalized diet plan based on the principles of the MD, paired with a lifestyle consultation for the promotion of PA for a total of 12 weeks, improved MD adherence in female patients with RA. Greater adherence to the MD was associated with an ameliorated dietary fat intake, BW, body composition, and lower disease activity state. Therefore, the adoption of the MD by patients with RA appears to be a feasible anti-inflammatory regime.

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Data Availability Statement: All data are available upon request to the first author.

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Protocol

Switching Mediterranean Consumers to Mediterranean Sustainable Healthy Dietary Patterns (SWITCHtoHEALTHY): Study Protocol of a Multicentric and Multi-Cultural Family-Based Nutritional Intervention Study

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Abstract: Background/Objectives: Populations in Mediterranean countries are abandoning the traditional Mediterranean diet (MD) and lifestyle, shifting towards unhealthier habits due to profound cultural and socioeconomic changes. The SWITCHtoHEALTHY project aims to demonstrate the effectiveness of a multi-component nutritional intervention to improve the adherence of families to the MD in three Mediterranean countries, thus prompting a dietary behavior change. Methods: A parallel, randomized, single-blinded, and controlled multicentric nutritional intervention study will be conducted over 3 months in 480 families with children and adolescents aged 3–17 years from Spain, Morocco, and Turkey. The multi-component intervention will combine digital interactive tools, hands-on educational materials, and easy-to-eat healthy snacks developed for this study. Through the developed SWITCHtoHEALTHY app, families will receive personalized weekly meal plans, which also consider what children eat at school. The engagement of all family members will be prompted by using a life simulation game. In addition, a set of activities and educational materials for adolescents based on a learning-through-playing approach will be codesigned. Innovative and sustainable plant-based snacks will be developed and introduced into the children's dietary plan as healthy alternatives for between meals. By using a full-factorial design, families will be randomized into eight groups (one control and seven interventions) to test the independent and combined effects of each component (application and/or educational materials and/or snacks). The impact of the intervention on diet quality, economy, and the environment, as well as on classical anthropometric parameters and vital signs, will be assessed in three different visits. The COM-B behavioral model will be used to assess essential factors driving the behavior change. The main outcome will be adherence to the MD assessed through MEDAS in adults and KIDMED in children and adolescents. Conclusions: SWITCHtoHEALTHY will provide new insights into the use of sustained models for inducing dietary and lifestyle behavior changes in the family setting. It will facilitate generating, boosting, and maintaining the switch to a healthier MD dietary pattern across the Mediterranean area. Registered Trial, National Institutes of Health, ClinicalTrials.gov (NCT06057324).

Keywords: Mediterranean diet; multicentric study; family intervention; educational materials; sustainability; digital tool; educational game; healthy snacks

1. Introduction

Currently, unhealthy diets are recognized as one of the most important risk factors in the development of noncommunicable diseases (NCDs). According to the Global Burden of Disease study (GBD) 1990–2019 [1,2], the consumption of unhealthy foods and nutrients, including sugar-sweetened beverages, red meat, and sodium, is far higher than the optimal intake in young and middle-aged adults. Diet modernization has led to a shift from traditional dietary patterns to more convenient, processed, and less nutritious food choices, with negative health consequences like overweight, obesity, diabetes, elevated blood pressure, and hyperlipidemia, all metabolic risk factors for NCDs [3]. In 2023, more than 150 million people suffered from NCDs in the Eastern Mediterranean region, with cardiovascular diseases (CVDs) accounting for 17.9 million deaths [3]. These figures corroborate the increasingly evident abandonment of the Mediterranean traditional dietary pattern [4].

The Mediterranean diet (MD) is linked to a set of skills, knowledge, practices, and traditions ranging from cultivation to the processing, preparation, and particularly the consumption of food and defines a unique lifestyle recognized as a common cultural heritage of Mediterranean communities [5]. It is essentially a plant-based dietary pattern based on the consumption of high amounts of fresh fruits, vegetables, and legumes as the main sources of fiber and antioxidant compounds and cereals (mainly whole grain), nuts, and olive oil as the main sources of fat. It also includes an abundance of fish and shellfish and a moderate consumption of white meat, eggs, and dairy products (mainly yogurt and cheese) [6,7]. The MD is a sustainable food model that is recognized as (a) environmentally sustainable, protecting biodiversity; (b) culturally acceptable and fair; (c) economically accessible and affordable; and (d) nutritionally adequate, safe, and healthy, as represented in the new environmental dimension of the MD pyramid [7,8]. According to the results of a recent meta-review, higher MD adherence scores were significantly associated with a reduced risk of CVD, type 2 diabetes, overall cancer mortality, different cognitive diseases, fractures, and metabolic syndrome, in addition to lower body weight, BMI, and blood pressure [9]. The available literature regarding MD adherence in children and adolescents from Mediterranean countries shows a higher percentage of young people with low MD adherence than with high adherence, according to the KIDMED index [10,11]. These findings suggest that several factors are contributing to the erosion of traditional Mediterranean dietary habits, among which cultural, socioeconomic, and lifestyle changes have a primary role [12]. The abandonment of traditional eating habits, the high consumption of precooked food, the low consumption of fresh, local, and seasonal products, and a sedentary lifestyle denote profound social changes in the current food culture of the Mediterranean region, especially among younger generations [4,12]. All of this is aggravated by the decline in agricultural biodiversity, largely due to globalizing trends, climate change, and the mechanization of farming practices, which reduce the sustainability of local production systems and, with it, our ability to safeguard the Mediterranean diet [13].

Nevertheless, parental factors need to be considered, especially when it comes to barriers and facilitators for children's dietary patterns. The family food environment becomes a strong predictor of children's food preferences and eating behaviors. Parental food habits and feeding strategies are the most dominant determinants of a child's food choices, which will persist throughout their life [14]. Some preliminary studies conducted with children and adolescents have found a significant positive correlation between MD adherence and family socioeconomic status, revealing that a higher MD adherence was associated with a better mother's education and income level [11]. In addition, in the PASOS study recently conducted in 3607 children and adolescents in Spain, adherence to the MD was higher in children and adolescents with healthier parental lifestyle [15].

It is believed that the social context most likely to induce healthy behavior changes is the family [16]. The reciprocal adult–child relationship represents a way of influencing the behavior of both children and adults. Lasting dietary changes are more likely when they involve the family unit because of the increased likelihood that family members will act and sustain behaviors and because of the beneficial familial social support. However, the current evidence of interventions aimed at improving dietary habits by involving all the family is limited [17,18]. Most of these interventions are focused on the prevention or treatment of child obesity, evaluating the effectiveness of improving diet quality at home on classical health variables such as body composition, glucose, and lipid profiles [19–21]. But, as far as we know, there is no family-based intervention aimed at improving the adherence to MD. Although many interventions carried out in schools have been shown to be effective in promoting a healthier dietary pattern, it is not fully determined if these interventions result in changed behavior outside the school setting [17,22]. In fact, an intervention comparing a family-based, school-based, and combined approach demonstrated that changes in parenting practices and healthy dietary behaviors were achieved among those exposed to the family intervention [23].

Recent trends show an emerging number of technology-based or eHealth interventions to improve health outcomes for lifestyle behaviors, particularly in young populations [24–27]. However, there is poor evidence of the effectiveness of family-based nutrition education programs engaging parents and/or parents and their children directly using digital tools such as mobile apps [28]. Most of the existing mobile apps promoting the MD lack family-based dietary guidance in terms of food preferences, sociocultural aspects, and other family-related parameters. Moreover, there is a need for complementary nutrition interventions to build a supportive environment for effective healthy eating in the household [28–30]. Codifying the pros and cons of using digital tools in health/dietary interventions, we note as benefits the possibility for personalized and adaptive guidance, the interactive engagement of all family members, the facilitation of easy, consistent, and ongoing support, the encouragement of self-monitoring and reflection, and the facilitation of education through experimental learning; and, as drawbacks, we mention digital divide and accessibility issues, challenges related to sustained engagement over time, family digital dynamics and differences in motivation to use digital tools, complexity and usability issues, and, finally, challenges related to privacy and data security.

In this context, the SWITCHtoHEALTHY project aims to generate a dietary behavior change by demonstrating and reinforcing the role of the family in promoting a sustainable change towards enhancing adherence to the Mediterranean dietary pattern of all the family members (adults, adolescents, and children). To achieve this goal, a randomized, single-blinded, and controlled multicentric nutritional intervention study, involving families from three Mediterranean countries (Spain, Turkey, and Morocco), will be carried out. The study will test the effectiveness of a holistic family-based approach that combines. (1) digital interactive tools (SWITCHtoHEALTHY app) designed to support parents in preparing weekly healthier dietary plans for all the family members; (2) hands-on educational materials and activities designed through a learning-through-playing approach to increase adolescents' knowledge and motivation on healthy and sustainable food habits; and (3) healthy and sustainable plant-based snacks to be introduced in children's dietary plans to substitute less healthy options between meals. The plant-based snacks, digital tools (app and game), and educational materials will be developed based on their effectiveness in promoting adherence to the MD, addressing common barriers Mediterranean families face in adopting healthier dietary habits.

The intervention is grounded in the COM-B model, part of the Behavior Change Wheel (BCW) framework, focusing on capability, opportunity, and motivation as key drivers of behavior change. It integrates Social Cognitive Theory (SCT) principles, emphasizing family-based support and digital engagement through tools. This combination aims to support MD adherence by targeting individual knowledge, family reinforcement, and accessible resources [31].

A sustained enabling environment will be promoted throughout the project to increase the awareness of an MD-based healthy diet and lifestyle model across the Mediterranean region in eight participating countries (SWITCHtoHEALTHY project; https://switchtohealthy.eu/ (accessed on 3 June 2024)), namely Spain, Italy, Greece, Turkey, Lebanon, Egypt, Tunisia, and Morocco, involving different research institutions with complementary expertise and resources within the areas of nutrition, eHealth, digital technologies/ICT, agro-food, food eco-design, innovation, R&D&I, and food manufacturing.

2. Materials and Methods

2.1. Study Design and Setting

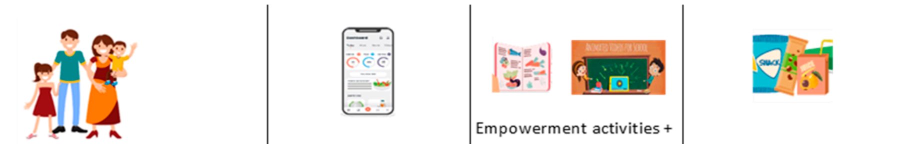
The SWITCHtoHEALTHY study is a parallel, randomized, single-blinded, and controlled multicentric nutritional intervention study. It aims to evaluate the effects of a multi-component intervention deployed at the family level, combining digital interactive tools and hands-on educational materials and activities with healthy and sustainable plant-based snacks, on the adherence to the MD pattern in 480 families with adolescents and children from three Mediterranean countries (Spain, Turkey, and Morocco), with 160 families per country. Secondarily, the effects of the multi-component intervention will be assessed according to lifestyle, anthropometric, dietary, sociodemographic, socioeconomic, and environmental indicators.

This study protocol was registered at ClinicalTrials.gov (NCT06057324) and is in accordance with the Helsinki Declaration and the Good Clinical Practice Guidelines on the International Conference of Harmonization. All the procedures described in the protocol, informed consent, and other documents have been reviewed and approved by the Ethics Committees of the three centers involved in the study: (1) Fundació Eurecat (study coordinator): Institut d'Investigació Sanitària Pere Virgili, IISPV (Ref. 135/2023); (2) Ethics Committee of Bursa Uludag University Faculty of Medicine Clinical Researches (Ref. 2023-23/29); and (3) Comité d'Ethique pour la Recherche Biomédicale (CERB), Université Mohammed V Faculté de Médecine et de Pharmacie de Rabat (preapproval). This protocol complies with the Standard Protocol Items: Recommendations for Clinical Trials (SPIRIT 2013 Statement and SPIRIT-AI extension) [32,33].

The 160 families recruited in each country will be randomly assigned into eight study groups (n = 20 families per group per country) according to a multi-component intervention including different combinations of the three study components (artificial intelligence (AI)-based app for all family; educational materials and empowerment activities for adolescents; and healthy plant-based snacks for children) and a control group that will receive basic Mediterranean guidelines for parents and their children (Figure 1).

To evaluate the overall effect of the intervention as well as the individual and combining effect of each intervention component, a full-factorial design will be used [34]. This design will allow us to evaluate the independent effect of the different intervention components versus the control group and, simultaneously, the summatory effect of combining different components on increasing the family adherence to the MD. This will therefore provide a stronger inference about the effect on the different implemented interventions [35].

The overall study duration will be 13 months for each participating family, including 3 main visits (V0, V1, and V2) (Figure 2). A prior preassessment visit will be performed at baseline, followed by the intervention study that will be deployed in the last 3 months (between month 10 and 13). According to this timeframe, this study will be arranged in two different phases (Figure 2).



	App for all family	Empowerment activities + Educational material	Snack for in-between meals
Control group (*n* =20)			
Intervention group 1 (*n* =20)	■		
Intervention group 2 (*n* =20)		■	
Intervention group 3 (*n* =20)			■
Intervention group 4 (*n* =20)	■	■	
Intervention group 5 (*n* =20)	■		■
Intervention group 6 (*n* =20)		■	■
Intervention group 7 (*n* =20)	■	■	■
n	80	80	80

Figure 1. Overview of the study groups.

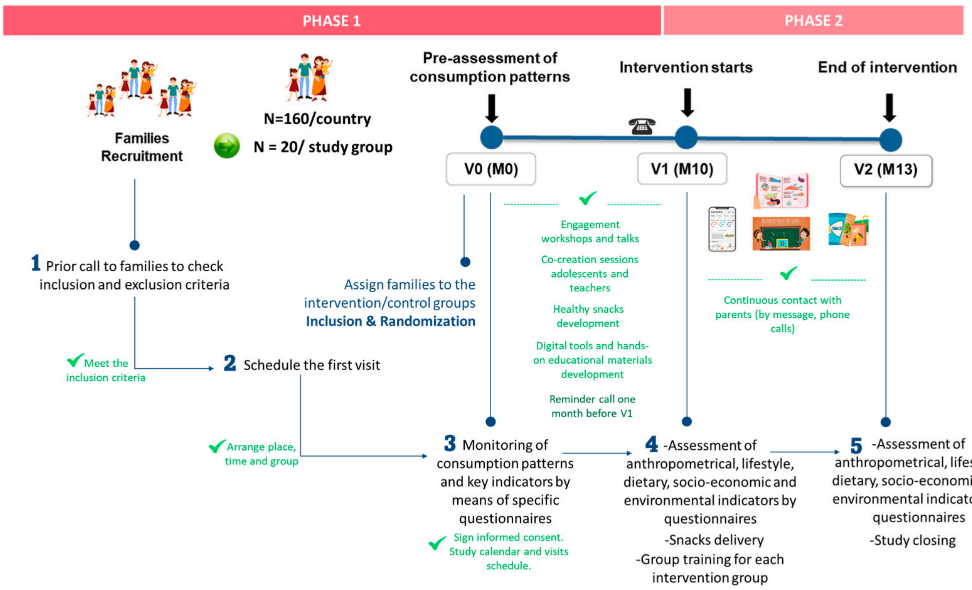


Figure 2. Timeframe and families' journey along the multicentric nutritional intervention study.

Phase 1 (*month 0 to month 9*): preassessment. The families will be recruited and included in this study; they will be randomly assigned to the different study groups; and consumption patterns and sociodemographic, socioeconomic, and environmental indicators will be evaluated through specific questionnaires. In addition, the different educational materials and activities, AI-based app, and healthy plant-based snacks will be developed prior to the start of the intervention study. This information will help us understand the context of each participant group and inform our analysis.

Phase 2 (*month 10 to month 13*): the intervention study will be deployed at the family level. Families will receive the educational materials and activities, the AI-based app, and the plant-based snacks developed in Phase 1, depending on their assigned intervention group. In addition, anthropometrics, lifestyle, dietary, and socioeconomic and environmental indicators will be evaluated through specific questionnaires.

2.2. Family Recruitment and Eligibility

The Spanish families will be recruited by researchers from the Nutrition and Health Unit (Eurecat, Reus) and the Center for Research in Agri-Food Economics and Development (CREDA, Barcelona), and the Turkish and Moroccan families will be recruited by researchers from the Bursa Uludag University and the Unité de Nutrition et al.imentation CNESTEN, respectively. In addition, all countries will have the support of schools, high schools, family associations, and other collaborators such as primary care centers and community centers.

Families will be eligible to participate if they meet the following criteria: (a) families from any socioeconomic status with at least one child younger than 12 years and one adolescent older than or equal to 12 years (overall age range 3–17 years) and that live together; (b) informed consent has been signed by parents and the adolescent; and (c) families have a mobile phone, tablet, or computer with internet access. This inclusion criterion of composition of families and ages of children was selected to capture a range of developmental stages within families, as younger children and adolescents may respond differently to dietary interventions than adults. While this may introduce differences in family structure, it also promotes interaction across ages, potentially enhancing the adoption of healthy eating habits through sibling influence and parental support.

Exclusion criteria will be as follows: (a) having allergies or food intolerances to any of the following plant-based snack ingredients: fruit, vegetables, legumes, cereals, seeds, nuts, and yogurt (only for children under 12 years); (b) disliking any of the snack products (only for children under 12 years); (c) MD Adherence Score (MEDAS) or KIDMED score greater than or equal to 11 points, which is a food pattern already highly concordant with the MD [36]; (d) following a vegan diet (any of the family members); (e) following a prescribed long-term and strict diet for any reason, including diets for weight loss and diets for chronic metabolic or autoimmune disorders such as type 1 diabetes, celiac disease, inflammatory bowel disease, or rheumatoid arthritis (any of the family members); (f) participating in or having participated in a clinical trial or nutritional intervention study in the last 30 days prior to inclusion in this study; (g) no or limited access to the internet; and (h) being unable to follow the study guidelines.

All recruited families will be interviewed by expert nutritionists to assess whether they meet the conditions for inclusion. For this purpose, two principal researchers in each country will be responsible for explaining the background, purpose, process, risks, and benefits of this study and obtaining informed consent.

2.3. Interventions

The interventions will involve a combination of digital-based tools and hands-on educational materials and activities, with healthy plant-based snacks developed during Phase 1 of this study. At the beginning of Phase 2 (month 10), there will be prior training for all families, where they will be informed about the specific intervention to which they will be randomly assigned.

The intervention materials and products will be adapted to reflect the cultural preferences and dietary habits of each country. This approach ensures that the interventions are relevant and engaging for families in each country. However, we will maintain some common elements across all interventions to facilitate meaningful comparisons in the study's outcomes.

2.3.1. Digital Interactive Tools

The digital interactive tools will be implemented in the form of an integrated web application, the "S2H app", which will be used by parents to empower them in their daily family dietary choices. The S2H app will be based on the integration of two separate dietary apps and an educational dietary game that will be designed, developed, technically validated, and extensively tested with real users during Phase 1 of the study: AI-based app for parents, app for children's Med-based dietary plan, and Digitami Game (Table 1). The two constituent dietary apps are, in turn, based on pre-existing technologies that have been validated in previous research projects with real users: the EU-funded PROTEIN project https://cordis.europa.eu/project/id/817732 (accessed on 9 September 2024) and the NUBI Parma app https://www.ailab.unipr.it/projects/ (accessed on 9

September 2024). Otherwise, the educational game will be developed entirely within the SWITCHtoHEALTHY project.

Table 1. Components of the S2H app.

App Component	Description
AI-Based App for Parents	The app will be accessible by parents from any device (including Android/iOS smartphones) through a web browser. The users will be able to provide basic profile information and receive personalized weekly meal plans adhering to a healthy and sustainable Mediterranean-based diet. The app will co-ordinate with the app for children's Med-based dietary plan to provide personalized weekly meal plans for all family members (parents, adolescents, and children).
App for Children's Med-Based Dietary Plan	The menus for children will complement the local school catering services (for nursery, kindergarten, and primary schools) and provide parents with ideas and suggestions about breakfast, snack, dinner, and weekend preparation, promoting a balanced food intake during the week. The app will thus consider what children eat in school canteens (based on the details provided by the school catering system), in the school café, and in what they bring in their lunch boxes from home (details provided by parents) and calculate possible complementary options for the rest of the day at home and for the weekend. In addition, educational materials, recipes, and daily tips are also provided to improve parents' culinary skills and nutrition knowledge, empowering them to manage the whole family's diet and to make proper food choices.
Digitami Game for All the Family	Digitami is an educational life simulation game to increase family engagement. It is envisioned as a "slow-paced" mobile game where the family members will have to take care of a "Tamagotchi" digital character living in the app, choosing and preparing their daily meals and/or physical activities to follow a balanced diet and a healthy lifestyle. Simultaneously, it will provide feedback about the nutritional value of the player's choices. Push notifications will be used to increase the engagement level of the family members.

The S2H app engine is fed with (a) expert-approved dietary rules; (b) user profile data for all family members; (c) school menus (from the school catering system) or, alternatively, lunch box contents and school café proposals; and (d) a list of representative meals of the local Mediterranean cuisine, i.e., breakfasts, lunches, and dinners, along with caloric and macronutrient information (the latter for the parents only). The seasonality of each food and ingredient and the culinary traditions of the food area in which the app is used are also considered. All the contents in the S2H app will be available in 4 languages (English, Spanish, Turkish, and Arabic).

The users will be able to provide basic profile information for each family member, including their year of birth, sex, physical characteristics (weight, height, and BMI), physical activity levels, dietary preferences, and history of food allergies, and will then receive weekly meal plans for them, adhering to a healthy and sustainable MD. Conversely, more general information will be requested for child users regarding age group, allergy to milk proteins, consumption of the project snacks, and school name (for school menu) or lunch box and school café alternatives.

2.3.2. Hands-On Educational Materials and Activities

The hands-on educational materials will be developed through a learning-through-playing approach to increase adolescents' knowledge and motivation on healthy and sustainable food habits according to sustainable MD patterns. An MD toolkit will be provided to adolescents and their families to educate them on the MD and associated health benefits to encourage the consumption of more healthy foods. The materials of the MD toolkit will be designed during Phase 1 of this study, including the following: (a) specific games and activities for adolescents, with proposed activities played at home with parents, brothers and sisters, and friends; (b) a range of resources, including educational fact sheets combining more theoretical notions about the MD model and optimal diet management (e.g., the "healthy eating plate", consumption frequencies, and food portions for different ages), infographics with take-home messages, recipes, and a short video. The educational materials will be available in different languages through the SWITCHtoHEALTHY website https://switchtohealthy.eu/ (accessed on 9 September 2024).

The educational activities will be part of an educational program specially designed to improve adherence to the MD of adolescents. The program will be conducted outside of school hours during the 3-month intervention and will be previously designed during Phase 1 of this study under the umbrella of three selected topics: (1) Mediterranean Diet and Lifestyle: discovering cultures, foods, and tastes; (2) Mediterranean Diet: from a healthy diet to a sustainable dietary pattern; and (3) Food Lab: kitchens from research or cooking centers as experimental hands-on zones for the application of healthy and sustainable dietary patterns. At least two cocreation sessions will be organized in each study country, with adolescents assigned to the educational activity groups as cocreators. The World Cafe Methodology [37–39] will be applied, encouraging participants to talk to each other and discuss the three selected topics in small groups in a cozy café-style space hosted by researchers as moderators (Ms) and high-school teachers as facilitators (Fs). Each session will take around one-and-a-half hours and will be joined by about 12 adolescents and at least 2 teachers and 2 researchers who will be neutral and encourage participation. The adolescents will be divided into three tables (4 to 5 adolescents per table) and, at each table, one of the three selected topics will be discussed so that the adolescents will rotate around every 20 min to participate in the discussion of all the topics (Figure 3). The researchers will record all the conversations that take place on a smartphone and will also take written notes. Once all the discussion rounds have finished and after a coffee break, the entire group will meet again in plenary. The resulting activities from each table will be summarized by researchers who will bring down the number of generated ideas to a handleable minimum, focusing on those factors generally considered to be the most important. Finally, the participants will vote on the results to prioritize actions to be implemented as educational activities in the frame of the educational program. After the cocreation session, all the data will be gathered and analyzed by the researchers in each country. The codesigned activities will then be reprioritized by all participants via an online survey. Lastly, the researchers will select and develop the 12 most voted educational activities, with 4 per topic, to be implemented within the framework of the intervention study.

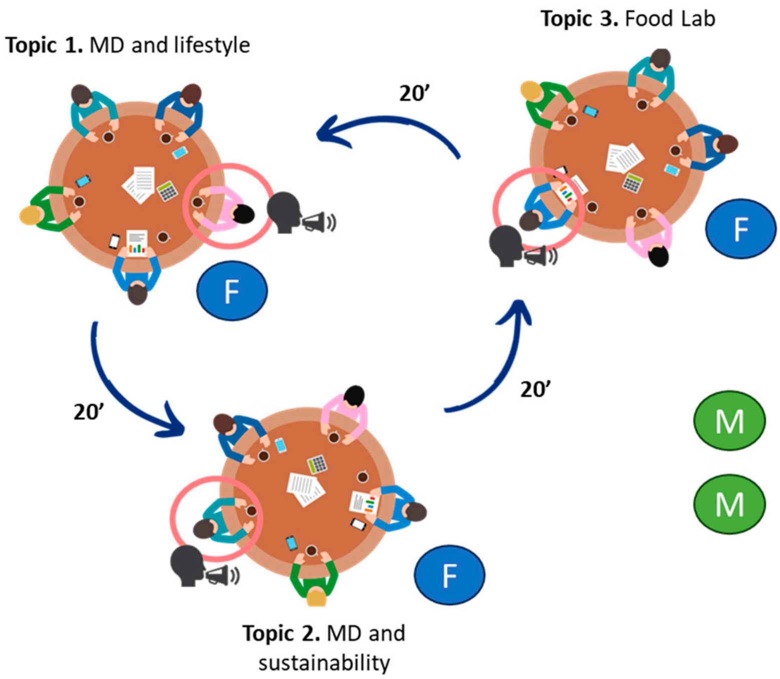


Figure 3. Codesign of educational activities: World Café Methodology.

During Phase 2 (month 10 to month 13), the codesigned activities will be carried out by adolescents at home (or in other nearby places, like markets) together with family and at research facilities together with the research staff. Four activities will be carried out on each selected topic in each month of intervention. Adolescents will be provided with a practical support handbook (or e-book) collecting all the activities and needed materials, which will be available and downloadable in different languages from the study website. Each activity will be described in the form of a didactic programing unit structured with the following sections: title, purpose, learning outcomes, preparation time and duration, methodology, materials required, and other resources. Due to the nature of this study, to avoid confounders in different intervention groups, these activities cannot be performed at school during the intervention. Nevertheless, the activity practical support handbook will be available for schoolteachers at the end of the intervention.

2.3.3. Healthy Plant-Based Snacks

The healthy and sustainable plant-based snacks will be developed and produced during Phase 1 of this study by three food companies located in Spain (DELAFRUIT S.L.U., Tarragona), Morocco (ECOMAB SARL, Casablanca), and Turkey (KOCAHAN SEKERLEME, Bursa) and will be consumed during the 3-month intervention by children aged 3 to 11 years.

The composition of the new food products will be based on local and traditional vegetables, fruits, legumes, seeds, and nuts as main ingredients, which are rich in health-promoting bioactive compounds. Processing and preservation strategies will be adapted to retain the nutritional value of the ingredients, and an eco-design methodology will be followed to produce the snacks [40]. In addition, the selection of the ingredients will be carried out beforehand in the three study countries through participatory focus groups involving parents and children. The locally produced plant-based ingredients will be presented to the families to determine their level of knowledge of them and the degree of incorporation in their diets (Table 2). The results of the focus group will allow the food manufacturers to reach a better understanding of the fruits, nuts, and vegetables the children usually consume in each country. Finally, after the preindustrial scale-up, four different snack prototypes to be used during the intervention in each country will be chosen according to the family's preferences, and the portions and frequency of consumption will be defined to complement the children's mid-morning and mid-afternoon snack, considering their nutritional and energy needs.

Table 2. List of ingredients presented to the families in the focus groups for each country.

Country	**List of Selected Ingredients**			
	Vegetables	**Fruits**	**Dried Fruits and Nuts**	**Legumes and Cereals**
Spain	Pumpkin Spinach Sweet potato	Mandarin Grape Peach Nopal Sumac	Almond Walnut Hazelnut	Chickpea Rice Grains
Turkey	Chicory Black carrot	Jujube Black fig Black mulberry Blueberry	Dates Dried apricot Almond Walnut Hazelnut	Chickpea powder Oatmeal

Table 2. *Cont.*

Country	List of Selected Ingredients			
	Vegetables	Fruits	Dried Fruits and Nuts	Legumes and Cereals
Morocco	Beetroot	Fig Orange Clementine Banana Apricot Apple Carob	Dates Almond Peanut Tigernut	Chickpea Whole wheat Oat

Since the snacks are produced with healthy and Mediterranean ingredients free of toxic agents and contaminants, no problems relating to children's safety are expected during the intervention study. At the time of family selection, the children's allergy history will be checked and the organoleptic characteristics of the snack products will be described to parents to verify the children's acceptance.

The snack products will be produced in a single batch in each country. Once produced, the manufacturers of each country will send them to the corresponding enrolment center prior to the start of the intervention study. The products will be delivered in a lot to the families in the same country at the beginning of the intervention.

2.4. Visits and Procedures

All families will attend the school facilities or at research centers where they are recruited on 3 different occasions (V0, V1, and V2). The visits will be divided between the two study phases previously described. Figure 4 shows the schedule of each visit, which will follow the same timeline for each enrollment center.

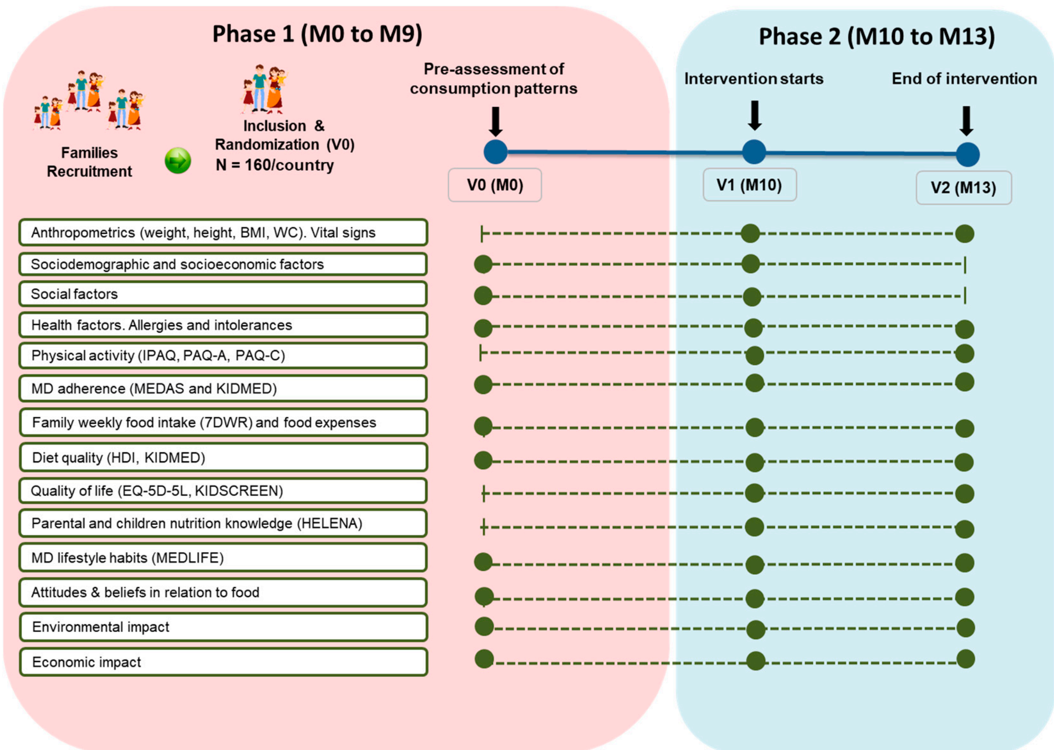


Figure 4. Description of study visits and outcomes.

In Phase 1, families will be recruited and a preassessment visit will be carried out (V0). At this point, families will be assessed against the eligibility criteria and then informed about this study in a group session. The informed consent document will be signed by parents and adolescents. The researchers will then instruct them on the completion of online questionnaires at home through the Microsoft Forms web-based application to assess socioeconomic, sociodemographic, lifestyle, and environmental indicators. This information will be valuable in predicting selected behavior sub-domains that will be evaluated based on a theoretical model derived from the COM-B model for behavior change. A theoretical model based on information on physical activity, food habits, lifestyle, and social behavior will be created, aiming to achieve the best outcomes via surveys that are not too long [41]. In addition, families will complete a 7-day semi-weighted food record (7DWR) to assess dietary habits and consumption patterns at baseline. After V0, the selected families will be randomly allocated to the different intervention/control groups.

In Phase 2, the selected families will attend V1 and V2 at the beginning and end of the 3-month intervention study, respectively. In V1, families will receive group training according to the different intervention groups: on the use of the S2H app, on snack consumption, and/or on the use of educational materials and activities. In addition, each family will be visited individually by expert nutritionists who will assess adherence to the MD through the MEDAS and KIDMED questionnaires for adults and children, respectively, and will take anthropometric measurements (body weight, height, BMI, waist circumference, blood pressure, and heart rate) for each family member. Nutritionists will also complete a medical history, including the use of medications and/or supplements. At the end of V1, time will be left for families to self-complete online questionnaires through the Microsoft Forms web-based application. The questionnaires will be adapted according to the age of the family members to assess socioeconomic, lifestyle, dietary, and environmental indicators. In addition, families will complete a 7DWR and report food expenses during the week after V1.

During the 3-month intervention, families will use the different educational components and products. They will be in continuous contact with the research team to ensure compliance and report any adverse events, particularly in children assigned to consume the snack products. In V2, each family will be visited individually, the same parameters as those in V1 will be measured by nutritionists, and data on socioeconomic, lifestyle, dietary, and environmental indicators will be self-reported by each family member by means of online questionnaires. A closing session of this study will be carried out by researchers once the intervention is completed to inform the families of the main results of the study.

2.5. Outcomes

The primary outcome will be adherence to the MD measured through the MEDAS and the KIDMED questionnaire score in parents and children, respectively. The MEDAS is an extension of a 9-point score developed in the Prevención con Dieta Mediterranea (PREDIMED) trial [42,43]. It consists of 2 questions about eating habits, 8 questions about the frequency of consumption of typical foods of the MD, and 4 questions about the consumption of foods not recommended in this diet. Each question is scored with 0 (non-compliant) or 1 (compliant), and the total score ranges from 0 to 14, so a score of 14 points means maximum adherence. The KIDMED score consists of 16 items with affirmative or negative answers, where there are 4 questions denoting a negative connotation to the MD and 12 questions denoting a positive connotation. A positive answer to questions denoting negative connotation is scored with −1, while positive connotation questions are scored with +1. The total score ranges from 0 to 12, so a score of 12 points indicates good adherence [44]. To avoid deviations in outcomes (such as physical activity or portions of food), surveys will be assessed by researchers during visits.

The secondary outcomes will include the following:

1. Anthropometric data: body weight, measured in all family members with a Tanita DC 430S-MA (Tanita Corp., Barcelona, Spain); height, obtained using a wall-mounted

stadiometer (Tanita Leicester Portable; Tanita Corp., Barcelona, Spain); waist circumference, measured at the level of the narrowest region between the last costal (10th rib) and the edge of the iliac crest using a 200 cm anthropometric steel measuring tape; and BMI, obtained using the formula of weight in kilograms divided by the square of the height in meters.

2. Systolic and diastolic blood pressure and resting heart rate, measured twice at 1 min intervals using an automatic sphygmomanometer (OMRON HEM-907; Peroxfarma, Barcelona, Spain).
3. Sociodemographic and socioeconomic factors, measured in parents and adolescents via an adapted questionnaire from Rodríguez-Rodríguez et al. [45]. This questionnaire will collect information regarding age, gender, household members, marital status, income, level of education, and employment status.
4. Social factors, measured in all family members via an adapted questionnaire from McIntosh et al. [46]. This questionnaire will collect information regarding work flexibility and satisfaction, work–life balance, lifestyle, time spent with children, family decision making, and task responsibility.
5. Physical activity, measured in all family members by validated physical activity questionnaires, IPAQ for adults [47] and PAQ-C [48] and PAQ-A [49] for children aged over 8 years and adolescents, respectively.
6. Health factors, measured in all family members via the General Health Questionnaire (GHQ) [50]. This questionnaire will ask about different aspects related to health and healthy lifestyle such as sleeping habits, hospitalization, and prescribed medications.
7. Mediterranean lifestyle habits, measured only in parents via the Mediterranean Lifestyle index (MEDLIFE), which will capture adherence to an overall Mediterranean healthy lifestyle [51].
8. Diet quality, measured via the Healthy Diet Index (HDI) [52] for adults and KIDMED [44] for adolescents and children.
9. Quality of life, measured via the EQ-5D-5L scale for adults [53] and the KIDSCREEN scale for adolescents and children aged over 8 years [54]. The EQ-5D-5L assesses five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The KIDSCREEN assesses children's and adolescents' subjective health and well-being.
10. Nutritional knowledge, measured via a short consumer-oriented nutrition knowledge questionnaire for adults [55] and the HELENA questionnaire for adolescents, which also includes a self-reported food frequency questionnaire [56]. These questionnaires will measure the parents' and adolescents' knowledge of a healthy diet.
11. Attitudes and beliefs in relation to food, measured via an adaptation of the McIntosh et al. questionnaire [46] and the Early Parenting Attitudes Questionnaire (EPAQ) [57]. These questionnaires will assess the family eating habits and attitudes of and barriers faced by parents and adolescents in relation to the MD.
12. Family weekly food intake, measured in all family members via a 7DWR, which involves an individual weighing of each food item prior to consumption. The 7DWR will be completed during the week after visit V0 and V1 and the week prior to visit V2. In V0, families will receive instructions for the correct completion. Nutritionists will instruct families on the use of kitchen scales. Apart from food, 7DWR will allow data on the average intake of macro- and micronutrients to be obtained.
13. Family weekly food expenses, measured per family unit using shopping receipts collected during the week after visit V0 and V1 and in the week prior to visit V2. In each visit, families will be provided with an envelope for collecting the shopping receipts and other food expenses for a week.
14. Environmental impact of food consumption, assessed by converting the 7DWR consumption quantities into kg of CO_2 emission, land use, and water footprint using existing data in the literature on the environmental impacts of different food groups [58–60].

15. Economic impact, estimated using the data obtained from family weekly food records and expenses reported by means of shopping receipts. Two measurements will be carried out at the beginning and end of the 3-month intervention, and potential effects of promotions at the specific retail outlet as well as family events and the seasonal effect will be controlled.

Each specific outcome and visit are summarized in Figure 4.

The integrated data from the primary and secondary outcomes, including MD adherence, diet quality, family weekly food intake, and food expenses, will provide an overview of the three main impact dimensions: quality of diet and health, economic, and environmental. These indicators will allow us to better understand the reasons behind dietary behavioral changes to facilitate the scaling-up of the most effective interventions or to redesign the less effective ones in the future.

2.6. Randomization and Allocation

After the baseline preassessment visit (V0), participating families will be randomized into the eight study groups. The randomization sequence list will be generated using the Randomization.com website (http://www.randomization.com) (accessed on 13 September 2024) by an external researcher not involved in this study. Stratified randomization, employing blocking, will be conducted to achieve a 1:1:1:1:1:1:1:1 ratio for the 7 intervention groups and the control group; $n = 60$ families per block. Due to the nature of the study, the families and the research staff cannot be blinded to the intervention, although the investigators who will perform the data analysis will work under concealment of the assignment.

2.7. Sample Size

The sample size was calculated based on differences in MD adherence score (primary outcome) measured by MEDAS and KIDMED questionnaires. The sample size was estimated using the analysis of variance (differences between 8 study groups). It was assumed that the alpha value would be equal to 0.05 and beta 0.20, exactly as reported in previous studies [61], with a common standard deviation equal to 1.19. The minimum group size needed to detect a minimum increase of 1 point in the intervention group's MEDAS compared to the control group is equal to 45 families per study group (15 families per country). The total sample is, therefore, $45 \times 8 = 360$ families. However, assuming a 25% drop-out rate, the minimum group size is equal to 60 families per study group (20 families per country). Overall, 160 families will thus be recruited per country after obtaining the approval of the Ethics Committee of each recruiting center and written informed consent from parents and adolescents.

2.8. Criteria for Discontinuing or Modifying Allocated Intervention

If a severe or unanticipated adverse event (AE) occurs that may influence the risk/benefit ratio of this study, the principal investigator must report this to the ethics committee and permanently discontinue the family from the intervention. Participating families will be asked to report any AEs experienced during the entire intervention. For each AE, the onset date, intensity, relationship to the study product, action taken, and outcome will be recorded by researchers in accordance with the Medical Dictionary for Regulatory Activities (MedDra dictionary), Version 24.0 of MedDRA (Spanish), March 2021. In case of the suspicion of a major AE, such as an allergic reaction, the case will be referred directly to the study doctor, who will evaluate the symptoms and signs and adopt the necessary measures according to their severity.

In addition, the researchers can withdraw a family from this study if they consider that the family can no longer meet all the requirements of the study or if any of the procedures are considered possibly harmful for any of its members. Families participating in the study will be withdrawn if they meet any of the following criteria: (1) any circumstance that prevents them from performing the study procedures (i.e., using the educational materials or digital interactive tools and complying with the intake of the study products); (2) not attending study visits.

The losses and dropouts will be carefully recorded to ensure study reliability. The next participant who meets the eligibility criteria will replace the last participant who withdraws from the research until reaching the calculated sample size.

2.9. Data Management

All data will be collected and evaluated by experienced researchers and registered by the same researchers or study participants through predesigned forms in the Microsoft Forms web-based application.

The online forms will be self-completed by families at home in V0 and at the research center or school facilities in V1 and V2 with the assistance of the research staff. The forms will be adapted from validated scales for adults, adolescents, and children, and translated into the language of each country (Spanish, Turkish, French, and Arabic). They will comprise nine blocks of questions assessing various factors of interest (attitudes, intentions, self-efficacy, time allocation, work and household stress, health, nutrition, etc.), all of them integrated using a theoretical framework matrix [46,55,62] (Table 3).

Table 3. Blocks of questions in the online forms for families.

Block	Assessed Factors
Socioeconomic factors	Age, gender, ethnicity, household members, marital status, income, level of education, and employment status
Social factors	Work flexibility and satisfaction, work–life balance, lifestyle, time spent with children, family decision making, and task responsibility
Psychological factors	Self-perception
Quality of life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression, and subjective well-being
Attitudes and beliefs related to food	Family eating habits and attitudes of and barriers faced by parents and adolescents related to the MD
Health and healthy lifestyle	Smoking, hospitalization, medication use, and sleep duration
Dietary habits	Eating rules, amount and type of food consumed, and food frequency intake
Nutritional knowledge	Level of knowledge of parents and adolescents on a healthy diet
Physical activity	Types and intensity of physical activity and sitting time spent as part of the individual's daily life

Each family will be provided access to the Microsoft Forms links with a unique code previously assigned. Each member of the family must complete their own forms, except for children under 8 years of age, who will need the help of their parents for completion. In total, parents must complete 3 forms, adolescents 2 forms, and children under 12 years of age only 1 form. The average time for parents to complete the forms is 40 min, while it will only take about 20 min for adolescents and children under 12 years.

Anthropometric measurements will be collected at V1 and V2 by trained nutritionists with specific devices and registered in an online data collection notebook available for each family member in the Microsoft Forms web-based application.

Data on consumption patterns will be recorded in writing format in a notebook including a 7DWR. For one week, families must record all the foods and drinks and the amount consumed for each member of the family. In addition, they will have to record food expenses and keep shopping receipts. The researchers will check the data provided and transfer them to a common Excel database for the three enrolled countries to assess the economic and environmental impact.

Data generated with Microsoft Forms will be exported to Microsoft Excel. Access to the database will be restricted only to authorized personnel of the research team. All participant data will be hosted by the responsible researcher in protected folders in the cloud of the institutional Microsoft OneDrive server located in the European Economic Area to guarantee privacy.

2.10. Statistical Analysis

2.10.1. Univariate Data Analysis

The data obtained from families in this study will be evaluated via an intention-to-treat (ITT) analysis, including data from families who drop out of the study, and per protocol (PP), that is, those families who have completed the treatment plan and who have exactly followed the instructions of the trial protocol. The error level of 0.05 will be set as a limit of statistical significance. A data analysis will be performed using the Statistical Software for Data Science (STATA, College Station, TX, USA) version 17.0 [63].

Mean and standard deviation will be reported for normally distributed variables and quantiles (25th percentile, median, and 75th percentile) for non-normally distributed variables. The Kolmogorov–Smirnov test and the Shapiro–Wilk test will be used to test for the normality of variables. The resulting scores of adherence to the MD (measured from the MEDAS and KIDMED questionnaires) will be used to calculate the mean differences between each intervention group and the control group before (V1) and after interventions (V2). Multiple comparisons (V2 vs. V0 and V2 vs. V1) of mean differences before and after interventions will be undertaken to assess the independent effect of interventions. The normality of the differences will be checked and, depending on the results, the following contrasts will be performed: parametric statistics (three-factor ANOVA with post hoc tests using the Bonferroni correction and considering the interactions between the following factors: app, educational materials, and snack products) will be used for normally distributed variables to compare differences in means and nonparametric statistics (Kruskal–Wallis test) will be used for non-normally distributed variables. Lineal regression and Spearman's method will be used to test for correlations between normal and non-normal outcome variables, respectively.

2.10.2. Multivariate Data Analysis

Structural equation modeling (SEM) is a multivariate, hypothesis-driven technique that is based on a structural model representing a hypothesis about the causal relations among several variables. It will integrate the multiple factors affecting the adherence to the MD, including economic factors, social factors, psychological factors, quality of life, attitudes and beliefs related to food, health and healthy lifestyle, dietary habits, nutritional knowledge, and physical activity. It will test the direct and indirect effects of these multiple factors on the adherence to the MD. Fit indices like the root mean square error of approximation (RMSEA), the Tucker–Lewis index (TLI), and the comparative fit index (CFI) will be used to check for the adequacy of the fit of the model.

We will monitor model fit indices (RMSEA, TLI, and CFI) to ensure they fall within acceptable ranges and adjust the SEM model structure as necessary based on theoretical and statistical considerations to maintain interpretability. Missing data will be handled using Full Information Maximum Likelihood (FIML) estimation, an approach suited to SEM that reduces bias by using all available data without directly imputing values. Additionally, we will evaluate patterns of missingness to determine if data are missing at random (MAR) or missing not at random (MNAR) and will justify our handling approach accordingly. The reliability will be checked using three criteria, including the internal consistency, composed reliability, and average variance extracted (AVE). Cronbach's alpha coefficient will be used to test the internal consistency of the scales. For validity, two criteria will be tested, including the convergent validity and the discriminant validity [62].

To address the socioeconomic and cultural differences among participants from Spain, Turkey, and Morocco, a stratified analysis will be conducted to examine the impact of socioeconomic and cultural contexts on participants' responses to the interventions. By categorizing participants based on key demographic variables such as income, education level, and cultural background, we can gain insights into how these factors influence dietary behaviors and adherence to the MD.

3. Discussion

The long-term feasibility of nutrition education programs is limited at the family level, so it has been suggested to use complementary nutrition interventions to build a supportive environment for effective healthy eating in the family setting [28]. To the best of our knowledge, the SWITCHtoHEALTHY study is the first multicentric nutritional intervention study assessing the effectiveness of a multi-component intervention to improve the adherence of Mediterranean families to the MD eating pattern through sustained changes in dietary behavior.

The novelty of the SWITCHtoHEALTHY study relies on the holistic family-based approach that combines and adapts different interactive tools, snack products, and methodologies designed to foster adherence to the MD of the different family members (parents, adolescents, and children) by considering their specific needs. The proposed approach involves the four main driving forces that, together, improve adherence to the MD eating pattern: sociocultural, economic, environmental, and health–nutritional [64].

Despite its well-known benefits, the MD is being abandoned or not adopted by young generations in most Mediterranean countries. The erosion of the MD dietary pattern in the modern era came with globalization, since it is often cheaper to import food from abroad than making local food available. Together with this, the increase in the consumption of ultra-processed food, food insecurity, and youth unemployment are all predisposing factors to unhealthy eating behavior [4,13]. In Spain, up to 69% of the child and adolescent population has been found to have suboptimal adherence to the MD according to the KIDMED index. The prevalence of low adherence is higher for secondary school than for primary school children [65,66]. In Moroccan and Turkish populations, only about 15% of adolescents have optimal adherence to the MD; among the factors associated with greater adherence, female gender, high monthly family income, and living in an apartment stand out [67–69]. In the same way, adolescents and young people living in Europe are far from being compliant with the nutritional recommendations for fruit, vegetables, legumes, and sodium, and they do not follow the principles of the MD [70,71]. Some factors positively associated with an optimal adherence to the MD are the mother's education level, the absence of distractions at breakfast, and regular physical activity, all factors that depend largely on the family environment [66].

Recently, healthy lifestyle-based interventions have been shown to be effective in increasing adherence to the MD and in achieving optimal adherence to this dietary pattern among children and adolescents [25,72]. According to a recent meta-analysis, greater improvements in achieving optimal adherence to the MD are found in interventions delivered out of school, those aimed at both children and parents, and those including participants with overweight/obesity [25]. The SWITCHtoHEALTHY intervention will adopt a "treat the family" approach to strengthen the adherence to the MD, focusing on the families and particularly families with children (kids and adolescents) for two main reasons: firstly, meals are one of the most important social activities among family members and one of the essences of the MD that is currently being abandoned; secondly, children's food habits are primarily acquired within families, and some of these food habits will persist over time. Families will be the unit of analysis as we try to understand the environmental factors affecting food consumption. Ultimately, this study aims to promote the MD by empowering families to be the actors of such behavioral change, generated from and for the family setting. This is a novelty when compared to other individual-driven interventions focused on specific age targets.

The use of the S2H app will support parents in preparing healthier weekly dietary plans, which will lead to greater adherence to the MD of the entire family. According to prior studies, technology-based interventions delivered via smartphone apps are successful in helping individuals achieve better improvements towards MD adherence in the short term [73] and have shown satisfactory usability, especially among young people [74]. Given the widespread use of digital devices, the potential of smartphone use in low- and middle-income countries has already been highlighted in the literature [75,76]. mHealth has been reported in the literature as a widely used tool to improve health outcomes for vulnerable communities in developing countries worldwide, such as those in Africa, Asia, and Latin America. The importance of implementing these methodologies according to the sociocultural needs of each population group is reiterated in the SWITCHtoHEALTHY project. The app developed within the project is based on the findings of a preliminary phase of research into the habits and needs of each individual country involved in this study. It also addresses this challenge by providing meal plans based on the MD, aligned with the cultural traditions of each participating country.

On the other hand, the development of novel healthy snack products has the potential to improve the contribution of essential nutrients in children's diets and, in the longer term, may reduce the impact of poor nutrition on public health [77]. Snacks are generally eaten between main meals, often with the intention of reducing or preventing hunger until the next meal. Healthy food options, such as fruits, nuts, and vegetables, should be promoted as between-meal snacks to avoid the consumption of energy-dense and processed foods like chips, biscuits, and sweets [78]. In this context, the SWITCHtoHEALTHY plant-based snacks will be made with a variety of local fruits, vegetables, legumes, and nuts to cover the nutritional needs of children in the mid-morning and mid-afternoon periods. It should be noted that the ingredients used for its preparation will be easily accessible in each country and can even be prepared in a similar way at home by families in the long term, for example, in the form of blends, purees, and bars.

The main strengths of this study are the multicentric nature of the intervention and the transferability and scalability of the educational materials designed in the frame of the project to be reproduced and replicated in other environments and countries beyond the project boundaries (e.g., workplaces, schools, campus canteens, and restaurants). During the intervention, the educational materials will be used at the family level to educate families on the MD and associated health benefits through a toolkit that combines information and tips to cook, prepare foods, benefits, and culture behind MD. In addition, adolescents will conduct educational activities codesigned with them that will reinforce their healthy dietary habits. Once the intervention ends, the materials could be used at the school level, serving as educational resources for teachers to become food educators. In fact, previous studies have shown the effectiveness of nutritional interventions led by trained teachers on improving adherence to the MD in schoolchildren, e.g., The Nutrition Education Teaching Pack (TP) funded by the Italian Ministry of Agricultural, Food, and Forestry Policies [79]. However, the adaptability of the materials is not exempt from challenges, especially when talking about populations outside the Mediterranean region. Materials may need adaptation to account for social and cultural differences. Local language translations would be essential to ensure accessibility and comprehension for participants from different linguistic backgrounds. Finally, resource availability, both in terms of foods typical of the MD and the economic means to procure them, would need to be addressed in any region-specific adaptation, ensuring alignment with local capacities and constraints.

On the other hand, the SWITCHtoHEALTHY study will play a key role in the achievement of a large part of the sustainable development goals (SDGs) linked to EU policies [80]. This will be, to a greater extent, possible through actions such as the transference of knowledge and skills for sustainable development; the valorization of food products from the traditional MD by using local plant varieties and eco-friendly food processing technologies; and the reduction in global food waste and the carbon footprint by promoting a sustainable consumption. In addition, it is expected that the intervention enhances food security and nutrition by providing personalized meal plans, improving diet quality indexes for at least 75% of participants.

Some potential limitations need to be considered. First, given that the dietary habits of children under 8 years of age will be answered by parents, it can suppose an underestimation or overestimation of the consumption of certain MD food groups, so the results could be biased. Second, the differences in socioeconomic and cultural factors among participating families could influence the changes in dietary habits given that certain typical

MD foods such as virgin olive oil may not be accessible to families with lower incomes. To account for this, our approach incorporates data collection on household income and food expenditure through structured questionnaires. This will allow us to analyze how financial factors impact dietary choices and adapt our strategies to accommodate families' economic realities. In addition, the fact that the interventions will take place in three different cultural areas could bias the results given different culinary traditions and beliefs around Mediterranean foods. Despite this, a tailored approach will be used for the design of menus and educational materials adapted to country specificities. Third, due to the nature of the interventions, participants and researchers cannot be blinded, although researchers who will perform the statistical analyses will be. Fourth, the gap in time between V0 and the start of the intervention (V1) can lead to a high drop-out rate of families. Another limitation is the use of the family as a unit of analysis, which means that all members must be involved and willing to lead the intervention to achieve change. Additionally, the short intervention period (3 months) might limit conclusions on the long-term effects. The three-month timeframe was chosen due to the limited duration of the project and the long time needed for the design of the study and the intervention components. This short-term assessment provides a foundation for understanding the intervention's immediate effectiveness and establishes groundwork for future studies to explore the long-term sustainability of MD adherence. Finally, families could experience a loss of adherence to the intervention components, particularly to the use of the app. The use of eHealth tools presupposes that users have a certain level of skills and competence (eHealth literacy) [81]. In this sense, the S2H app will be user-friendly and universally accessible, and it will have a usability monitoring system.

Regarding the long-term adoption of healthy eating habits at the family level through multi-component interventions such as those proposed in this study, it is worth considering some barriers that may hinder adherence to interventions such as antisocial behavior during adolescence or the lack of parental engagement due to lack of time. For this reason, family-based interventions may focus on the provision of skills, knowledge, and support; frequency and quality of parent–child communications; and reinforcement of shared values and behaviors ensuring the involvement of all family members [17]. The holistic family-based approach planned for the SWITCHtoHEALTHY study will consider all these barriers associated with family behavior. Furthermore, the use of development methodologies such as the learning-through-playing approach will encourage children and adolescents to develop cognitive and communication skills, learn to manage their emotional states, and gain self-confidence for changing their eating behaviors [82].

While this study focuses on promoting adherence to the core components of the MD, such as the increased consumption of fruits, vegetables, whole grains, legumes, and extra virgin olive oil, we acknowledge the recent shifts in dietary habits in Mediterranean countries. The rising intake of ultra-processed foods and the use of oils other than extra virgin olive oil are noteworthy trends that may influence adherence to traditional dietary patterns.

The multidisciplinary consortium will facilitate the exchange of best practices among Mediterranean basin countries to create common knowledge and understanding on the impact of greater adherence to the MD at the health, environmental, and economic level. It will facilitate generating, boosting, and maintaining the switch to a healthier Mediterranean dietary pattern across the Mediterranean area. The key findings generated will be translated into the development of new future strategies to increase the adaptation of individuals to the MD by encouraging nutritionally adequate, healthy, and sustainable behaviors [83]. The results will be summarized, and recommendations will be prepared for government bodies, public health institutions, and NGOs across the Mediterranean. These documents will translate scientific results into actionable policies. In addition, a series of workshops and roundtables will be organized in collaboration with national health ministries and local authorities in Spain, Morocco, and Turkey. The most impactful components (e.g., plant-based snacks and digital tools) will be proposed for inclusion in national and regional health programs, with the support of cost–benefit analyses demonstrating their scalability and sustainability. By employing these mechanisms, SWITCHtoHEALTHY aims to ensure that its findings do not remain confined to the academic sphere but are translated into practical strategies adopted by policymakers and public health institutions across the Mediterranean region.

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Informed Consent Statement: Informed consent will be obtained from all subjects involved in this study.

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nutrients

MDPI

Protocol

Switching Mediterranean Consumers to Mediterranean Sustainable Healthy Dietary Patterns (SWITCHtoHEALTHY): Study Protocol of a Multicentric and Multi-Cultural Family-Based Nutritional Intervention Study

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Abstract: Background/Objectives: Populations in Mediterranean countries are abandoning the traditional Mediterranean diet (MD) and lifestyle, shifting towards unhealthier habits due to profound cultural and socioeconomic changes. The SWITCHtoHEALTHY project aims to demonstrate the effectiveness of a multi-component nutritional intervention to improve the adherence of families to the MD in three Mediterranean countries, thus prompting a dietary behavior change. Methods: A parallel, randomized, single-blinded, and controlled multicentric nutritional intervention study will be conducted over 3 months in 480 families with children and adolescents aged 3–17 years from Spain, Morocco, and Turkey. The multi-component intervention will combine digital interactive tools, hands-on educational materials, and easy-to-eat healthy snacks developed for this study. Through the developed SWITCHtoHEALTHY app, families will receive personalized weekly meal plans, which also consider what children eat at school. The engagement of all family members will be prompted by using a life simulation game. In addition, a set of activities and educational materials for adolescents based on a learning-through-playing approach will be codesigned. Innovative and sustainable plant-based snacks will be developed and introduced into the children's dietary plan as healthy alternatives for between meals. By using a full-factorial design, families will be randomized into eight groups (one control and seven interventions) to test the independent and combined effects of each component (application and/or educational materials and/or snacks). The impact of the intervention on diet quality, economy, and the environment, as well as on classical anthropometric parameters and vital signs, will be assessed in three different visits. The COM-B behavioral model will be used to assess essential factors driving the behavior change. The main outcome will be adherence to the MD assessed through MEDAS in adults and KIDMED in children and adolescents. Conclusions: SWITCHtoHEALTHY will provide new insights into the use of sustained models for inducing dietary and lifestyle behavior changes in the family setting. It will facilitate generating, boosting, and maintaining the switch to a healthier MD dietary pattern across the Mediterranean area. Registered Trial, National Institutes of Health, ClinicalTrials.gov (NCT06057324).

Keywords: Mediterranean diet; multicentric study; family intervention; educational materials; sustainability; digital tool; educational game; healthy snacks

1. Introduction

Currently, unhealthy diets are recognized as one of the most important risk factors in the development of noncommunicable diseases (NCDs). According to the Global Burden of Disease study (GBD) 1990–2019 [1,2], the consumption of unhealthy foods and nutrients, including sugar-sweetened beverages, red meat, and sodium, is far higher than the optimal intake in young and middle-aged adults. Diet modernization has led to a shift from traditional dietary patterns to more convenient, processed, and less nutritious food choices, with negative health consequences like overweight, obesity, diabetes, elevated blood pressure, and hyperlipidemia, all metabolic risk factors for NCDs [3]. In 2023, more than 150 million people suffered from NCDs in the Eastern Mediterranean region, with cardiovascular diseases (CVDs) accounting for 17.9 million deaths [3]. These figures corroborate the increasingly evident abandonment of the Mediterranean traditional dietary pattern [4].

The Mediterranean diet (MD) is linked to a set of skills, knowledge, practices, and traditions ranging from cultivation to the processing, preparation, and particularly the consumption of food and defines a unique lifestyle recognized as a common cultural heritage of Mediterranean communities [5]. It is essentially a plant-based dietary pattern based on the consumption of high amounts of fresh fruits, vegetables, and legumes as the main sources of fiber and antioxidant compounds and cereals (mainly whole grain), nuts, and olive oil as the main sources of fat. It also includes an abundance of fish and shellfish and a moderate consumption of white meat, eggs, and dairy products (mainly yogurt and cheese) [6,7]. The MD is a sustainable food model that is recognized as (a) environmentally sustainable, protecting biodiversity; (b) culturally acceptable and fair; (c) economically accessible and affordable; and (d) nutritionally adequate, safe, and healthy, as represented in the new environmental dimension of the MD pyramid [7,8]. According to the results of a recent meta-review, higher MD adherence scores were significantly associated with a reduced risk of CVD, type 2 diabetes, overall cancer mortality, different cognitive diseases, fractures, and metabolic syndrome, in addition to lower body weight, BMI, and blood pressure [9]. The available literature regarding MD adherence in children and adolescents from Mediterranean countries shows a higher percentage of young people with low MD adherence than with high adherence, according to the KIDMED index [10,11]. These findings suggest that several factors are contributing to the erosion of traditional Mediterranean dietary habits, among which cultural, socioeconomic, and lifestyle changes have a primary role [12]. The abandonment of traditional eating habits, the high consumption of precooked food, the low consumption of fresh, local, and seasonal products, and a sedentary lifestyle denote profound social changes in the current food culture of the Mediterranean region, especially among younger generations [4,12]. All of this is aggravated by the decline in agricultural biodiversity, largely due to globalizing trends, climate change, and the mechanization of farming practices, which reduce the sustainability of local production systems and, with it, our ability to safeguard the Mediterranean diet [13].

Nevertheless, parental factors need to be considered, especially when it comes to barriers and facilitators for children's dietary patterns. The family food environment becomes a strong predictor of children's food preferences and eating behaviors. Parental food habits and feeding strategies are the most dominant determinants of a child's food choices, which will persist throughout their life [14]. Some preliminary studies conducted with children and adolescents have found a significant positive correlation between MD adherence and family socioeconomic status, revealing that a higher MD adherence was associated with a better mother's education and income level [11]. In addition, in the PASOS study recently conducted in 3607 children and adolescents in Spain, adherence to the MD was higher in children and adolescents with healthier parental lifestyle [15].

It is believed that the social context most likely to induce healthy behavior changes is the family [16]. The reciprocal adult–child relationship represents a way of influencing the behavior of both children and adults. Lasting dietary changes are more likely when they involve the family unit because of the increased likelihood that family members will act and sustain behaviors and because of the beneficial familial social support. However, the current evidence of interventions aimed at improving dietary habits by involving all the family is limited [17,18]. Most of these interventions are focused on the prevention or treatment of child obesity, evaluating the effectiveness of improving diet quality at home on classical health variables such as body composition, glucose, and lipid profiles [19–21]. But, as far as we know, there is no family-based intervention aimed at improving the adherence to MD. Although many interventions carried out in schools have been shown to be effective in promoting a healthier dietary pattern, it is not fully determined if these interventions result in changed behavior outside the school setting [17,22]. In fact, an intervention comparing a family-based, school-based, and combined approach demonstrated that changes in parenting practices and healthy dietary behaviors were achieved among those exposed to the family intervention [23].

Recent trends show an emerging number of technology-based or eHealth interventions to improve health outcomes for lifestyle behaviors, particularly in young populations [24–27]. However, there is poor evidence of the effectiveness of family-based nutrition education programs engaging parents and/or parents and their children directly using digital tools such as mobile apps [28]. Most of the existing mobile apps promoting the MD lack family-based dietary guidance in terms of food preferences, sociocultural aspects, and other family-related parameters. Moreover, there is a need for complementary nutrition interventions to build a supportive environment for effective healthy eating in the household [28–30]. Codifying the pros and cons of using digital tools in health/dietary interventions, we note as benefits the possibility for personalized and adaptive guidance, the interactive engagement of all family members, the facilitation of easy, consistent, and ongoing support, the encouragement of self-monitoring and reflection, and the facilitation of education through experimental learning; and, as drawbacks, we mention digital divide and accessibility issues, challenges related to sustained engagement over time, family digital dynamics and differences in motivation to use digital tools, complexity and usability issues, and, finally, challenges related to privacy and data security.

In this context, the SWITCHtoHEALTHY project aims to generate a dietary behavior change by demonstrating and reinforcing the role of the family in promoting a sustainable change towards enhancing adherence to the Mediterranean dietary pattern of all the family members (adults, adolescents, and children). To achieve this goal, a randomized, single-blinded, and controlled multicentric nutritional intervention study, involving families from three Mediterranean countries (Spain, Turkey, and Morocco), will be carried out. The study will test the effectiveness of a holistic family-based approach that combines. (1) digital interactive tools (SWITCHtoHEALTHY app) designed to support parents in preparing weekly healthier dietary plans for all the family members; (2) hands-on educational materials and activities designed through a learning-through-playing approach to increase adolescents' knowledge and motivation on healthy and sustainable food habits; and (3) healthy and sustainable plant-based snacks to be introduced in children's dietary plans to substitute less healthy options between meals. The plant-based snacks, digital tools (app and game), and educational materials will be developed based on their effectiveness in promoting adherence to the MD, addressing common barriers Mediterranean families face in adopting healthier dietary habits.

The intervention is grounded in the COM-B model, part of the Behavior Change Wheel (BCW) framework, focusing on capability, opportunity, and motivation as key drivers of behavior change. It integrates Social Cognitive Theory (SCT) principles, emphasizing family-based support and digital engagement through tools. This combination aims to support MD adherence by targeting individual knowledge, family reinforcement, and accessible resources [31].

A sustained enabling environment will be promoted throughout the project to increase the awareness of an MD-based healthy diet and lifestyle model across the Mediterranean region in eight participating countries (SWITCHtoHEALTHY project; https://switchtohealthy.eu/ (accessed on 3 June 2024)), namely Spain, Italy, Greece, Turkey, Lebanon, Egypt, Tunisia, and Morocco, involving different research institutions with complementary expertise and resources within the areas of nutrition, eHealth, digital technologies/ICT, agro-food, food eco-design, innovation, R&D&I, and food manufacturing.

2. Materials and Methods

2.1. Study Design and Setting

The SWITCHtoHEALTHY study is a parallel, randomized, single-blinded, and controlled multicentric nutritional intervention study. It aims to evaluate the effects of a multi-component intervention deployed at the family level, combining digital interactive tools and hands-on educational materials and activities with healthy and sustainable plant-based snacks, on the adherence to the MD pattern in 480 families with adolescents and children from three Mediterranean countries (Spain, Turkey, and Morocco), with 160 families per country. Secondarily, the effects of the multi-component intervention will be assessed according to lifestyle, anthropometric, dietary, sociodemographic, socioeconomic, and environmental indicators.

This study protocol was registered at ClinicalTrials.gov (NCT06057324) and is in accordance with the Helsinki Declaration and the Good Clinical Practice Guidelines on the International Conference of Harmonization. All the procedures described in the protocol, informed consent, and other documents have been reviewed and approved by the Ethics Committees of the three centers involved in the study: (1) Fundació Eurecat (study coordinator): Institut d'Investigació Sanitària Pere Virgili, IISPV (Ref. 135/2023); (2) Ethics Committee of Bursa Uludag University Faculty of Medicine Clinical Researches (Ref. 2023-23/29); and (3) Comité d'Ethique pour la Recherche Biomédicale (CERB), Université Mohammed V Faculté de Médecine et de Pharmacie de Rabat (preapproval). This protocol complies with the Standard Protocol Items: Recommendations for Clinical Trials (SPIRIT 2013 Statement and SPIRIT-AI extension) [32,33].

The 160 families recruited in each country will be randomly assigned into eight study groups (n = 20 families per group per country) according to a multi-component intervention including different combinations of the three study components (artificial intelligence (AI)-based app for all family; educational materials and empowerment activities for adolescents; and healthy plant-based snacks for children) and a control group that will receive basic Mediterranean guidelines for parents and their children (Figure 1).

To evaluate the overall effect of the intervention as well as the individual and combining effect of each intervention component, a full-factorial design will be used [34]. This design will allow us to evaluate the independent effect of the different intervention components versus the control group and, simultaneously, the summatory effect of combining different components on increasing the family adherence to the MD. This will therefore provide a stronger inference about the effect on the different implemented interventions [35].

The overall study duration will be 13 months for each participating family, including 3 main visits (V0, V1, and V2) (Figure 2). A prior preassessment visit will be performed at baseline, followed by the intervention study that will be deployed in the last 3 months (between month 10 and 13). According to this timeframe, this study will be arranged in two different phases (Figure 2).

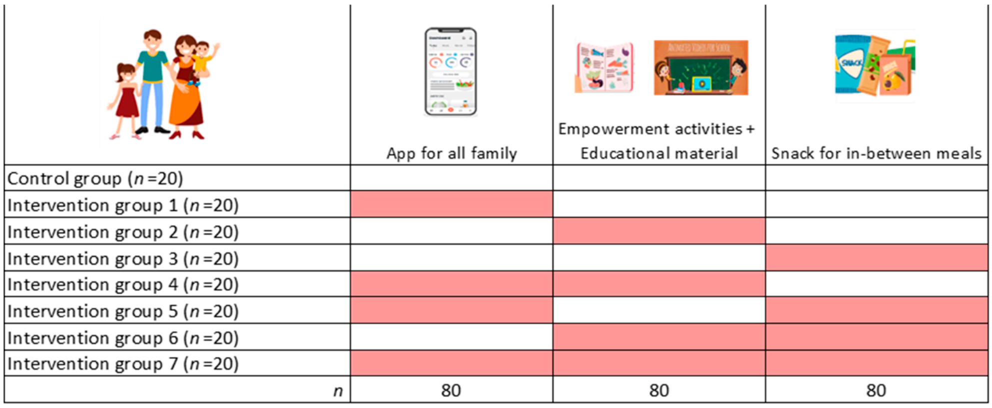

Figure 1. Overview of the study groups.

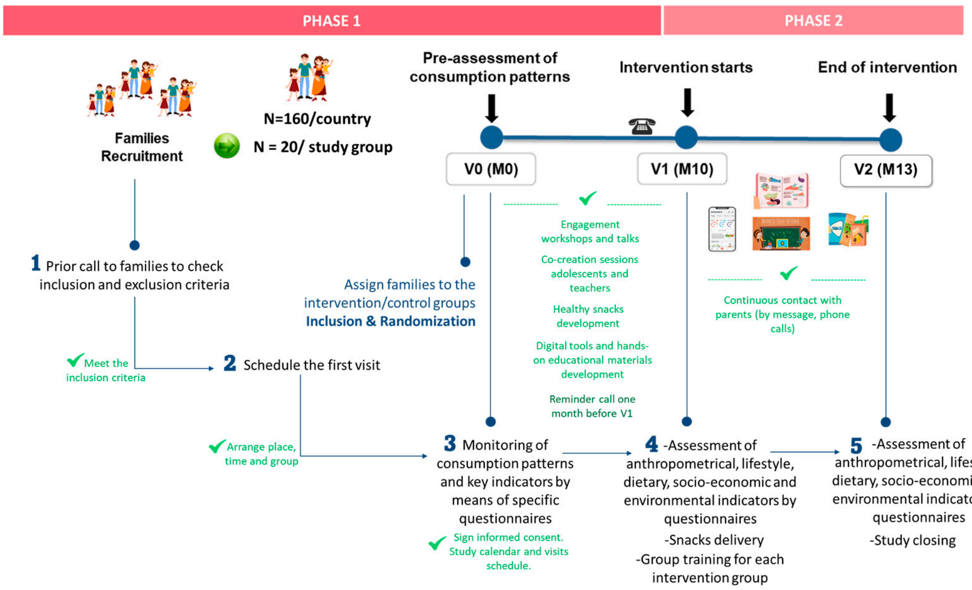

Figure 2. Timeframe and families' journey along the multicentric nutritional intervention study.

Phase 1 (*month 0 to month 9*): preassessment. The families will be recruited and included in this study; they will be randomly assigned to the different study groups; and consumption patterns and sociodemographic, socioeconomic, and environmental indicators will be evaluated through specific questionnaires. In addition, the different educational materials and activities, AI-based app, and healthy plant-based snacks will be developed prior to the start of the intervention study. This information will help us understand the context of each participant group and inform our analysis.

Phase 2 (*month 10 to month 13*): the intervention study will be deployed at the family level. Families will receive the educational materials and activities, the AI-based app, and the plant-based snacks developed in Phase 1, depending on their assigned intervention group. In addition, anthropometrics, lifestyle, dietary, and socioeconomic and environmental indicators will be evaluated through specific questionnaires.

2.2. Family Recruitment and Eligibility

The Spanish families will be recruited by researchers from the Nutrition and Health Unit (Eurecat, Reus) and the Center for Research in Agri-Food Economics and Development (CREDA, Barcelona), and the Turkish and Moroccan families will be recruited by researchers from the Bursa Uludag University and the Unité de Nutrition et al.imentation CNESTEN, respectively. In addition, all countries will have the support of schools, high schools, family associations, and other collaborators such as primary care centers and community centers.

Families will be eligible to participate if they meet the following criteria: (a) families from any socioeconomic status with at least one child younger than 12 years and one adolescent older than or equal to 12 years (overall age range 3–17 years) and that live together; (b) informed consent has been signed by parents and the adolescent; and (c) families have a mobile phone, tablet, or computer with internet access. This inclusion criterion of composition of families and ages of children was selected to capture a range of developmental stages within families, as younger children and adolescents may respond differently to dietary interventions than adults. While this may introduce differences in family structure, it also promotes interaction across ages, potentially enhancing the adoption of healthy eating habits through sibling influence and parental support.

Exclusion criteria will be as follows: (a) having allergies or food intolerances to any of the following plant-based snack ingredients: fruit, vegetables, legumes, cereals, seeds, nuts, and yogurt (only for children under 12 years); (b) disliking any of the snack products (only for children under 12 years); (c) MD Adherence Score (MEDAS) or KIDMED score greater than or equal to 11 points, which is a food pattern already highly concordant with the MD [36]; (d) following a vegan diet (any of the family members); (e) following a prescribed long-term and strict diet for any reason, including diets for weight loss and diets for chronic metabolic or autoimmune disorders such as type 1 diabetes, celiac disease, inflammatory bowel disease, or rheumatoid arthritis (any of the family members); (f) participating in or having participated in a clinical trial or nutritional intervention study in the last 30 days prior to inclusion in this study; (g) no or limited access to the internet; and (h) being unable to follow the study guidelines.

All recruited families will be interviewed by expert nutritionists to assess whether they meet the conditions for inclusion. For this purpose, two principal researchers in each country will be responsible for explaining the background, purpose, process, risks, and benefits of this study and obtaining informed consent.

2.3. Interventions

The interventions will involve a combination of digital-based tools and hands-on educational materials and activities, with healthy plant-based snacks developed during Phase 1 of this study. At the beginning of Phase 2 (month 10), there will be prior training for all families, where they will be informed about the specific intervention to which they will be randomly assigned.

The intervention materials and products will be adapted to reflect the cultural preferences and dietary habits of each country. This approach ensures that the interventions are relevant and engaging for families in each country. However, we will maintain some common elements across all interventions to facilitate meaningful comparisons in the study's outcomes.

2.3.1. Digital Interactive Tools

The digital interactive tools will be implemented in the form of an integrated web application, the "S2H app", which will be used by parents to empower them in their daily family dietary choices. The S2H app will be based on the integration of two separate dietary apps and an educational dietary game that will be designed, developed, technically validated, and extensively tested with real users during Phase 1 of the study: AI-based app for parents, app for children's Med-based dietary plan, and Digitami Game (Table 1). The two constituent dietary apps are, in turn, based on pre-existing technologies that have been validated in previous research projects with real users: the EU-funded PROTEIN project https://cordis.europa.eu/project/id/817732 (accessed on 9 September 2024) and the NUBI Parma app https://www.ailab.unipr.it/projects/ (accessed on 9

September 2024). Otherwise, the educational game will be developed entirely within the SWITCHtoHEALTHY project.

Table 1. Components of the S2H app.

App Component	Description
AI-Based App for Parents	The app will be accessible by parents from any device (including Android/iOS smartphones) through a web browser. The users will be able to provide basic profile information and receive personalized weekly meal plans adhering to a healthy and sustainable Mediterranean-based diet. The app will co-ordinate with the app for children's Med-based dietary plan to provide personalized weekly meal plans for all family members (parents, adolescents, and children).
App for Children's Med-Based Dietary Plan	The menus for children will complement the local school catering services (for nursery, kindergarten, and primary schools) and provide parents with ideas and suggestions about breakfast, snack, dinner, and weekend preparation, promoting a balanced food intake during the week. The app will thus consider what children eat in school canteens (based on the details provided by the school catering system), in the school café, and in what they bring in their lunch boxes from home (details provided by parents) and calculate possible complementary options for the rest of the day at home and for the weekend. In addition, educational materials, recipes, and daily tips are also provided to improve parents' culinary skills and nutrition knowledge, empowering them to manage the whole family's diet and to make proper food choices.
Digitami Game for All the Family	Digitami is an educational life simulation game to increase family engagement. It is envisioned as a "slow-paced" mobile game where the family members will have to take care of a "Tamagotchi" digital character living in the app, choosing and preparing their daily meals and/or physical activities to follow a balanced diet and a healthy lifestyle. Simultaneously, it will provide feedback about the nutritional value of the player's choices. Push notifications will be used to increase the engagement level of the family members.

The S2H app engine is fed with (a) expert-approved dietary rules; (b) user profile data for all family members; (c) school menus (from the school catering system) or, alternatively, lunch box contents and school café proposals; and (d) a list of representative meals of the local Mediterranean cuisine, i.e., breakfasts, lunches, and dinners, along with caloric and macronutrient information (the latter for the parents only). The seasonality of each food and ingredient and the culinary traditions of the food area in which the app is used are also considered. All the contents in the S2H app will be available in 4 languages (English, Spanish, Turkish, and Arabic).

The users will be able to provide basic profile information for each family member, including their year of birth, sex, physical characteristics (weight, height, and BMI), physical activity levels, dietary preferences, and history of food allergies, and will then receive weekly meal plans for them, adhering to a healthy and sustainable MD. Conversely, more general information will be requested for child users regarding age group, allergy to milk proteins, consumption of the project snacks, and school name (for school menu) or lunch box and school café alternatives.

2.3.2. Hands-On Educational Materials and Activities

The hands-on educational materials will be developed through a learning-through-playing approach to increase adolescents' knowledge and motivation on healthy and sustainable food habits according to sustainable MD patterns. An MD toolkit will be provided to adolescents and their families to educate them on the MD and associated health benefits to encourage the consumption of more healthy foods. The materials of the MD toolkit will be designed during Phase 1 of this study, including the following: (a) specific games and activities for adolescents, with proposed activities played at home with parents, brothers and sisters, and friends; (b) a range of resources, including educational fact sheets combining more theoretical notions about the MD model and optimal diet management (e.g., the "healthy eating plate", consumption frequencies, and food portions for different ages), infographics with take-home messages, recipes, and a short video. The educational materials will be available in different languages through the SWITCHtoHEALTHY website https://switchtohealthy.eu/ (accessed on 9 September 2024).

The educational activities will be part of an educational program specially designed to improve adherence to the MD of adolescents. The program will be conducted outside of school hours during the 3-month intervention and will be previously designed during Phase 1 of this study under the umbrella of three selected topics: (1) Mediterranean Diet and Lifestyle: discovering cultures, foods, and tastes; (2) Mediterranean Diet: from a healthy diet to a sustainable dietary pattern; and (3) Food Lab: kitchens from research or cooking centers as experimental hands-on zones for the application of healthy and sustainable dietary patterns. At least two cocreation sessions will be organized in each study country, with adolescents assigned to the educational activity groups as cocreators. The World Cafe Methodology [37–39] will be applied, encouraging participants to talk to each other and discuss the three selected topics in small groups in a cozy café-style space hosted by researchers as moderators (Ms) and high-school teachers as facilitators (Fs). Each session will take around one-and-a-half hours and will be joined by about 12 adolescents and at least 2 teachers and 2 researchers who will be neutral and encourage participation. The adolescents will be divided into three tables (4 to 5 adolescents per table) and, at each table, one of the three selected topics will be discussed so that the adolescents will rotate around every 20 min to participate in the discussion of all the topics (Figure 3). The researchers will record all the conversations that take place on a smartphone and will also take written notes. Once all the discussion rounds have finished and after a coffee break, the entire group will meet again in plenary. The resulting activities from each table will be summarized by researchers who will bring down the number of generated ideas to a handleable minimum, focusing on those factors generally considered to be the most important. Finally, the participants will vote on the results to prioritize actions to be implemented as educational activities in the frame of the educational program. After the cocreation session, all the data will be gathered and analyzed by the researchers in each country. The codesigned activities will then be reprioritized by all participants via an online survey. Lastly, the researchers will select and develop the 12 most voted educational activities, with 4 per topic, to be implemented within the framework of the intervention study.

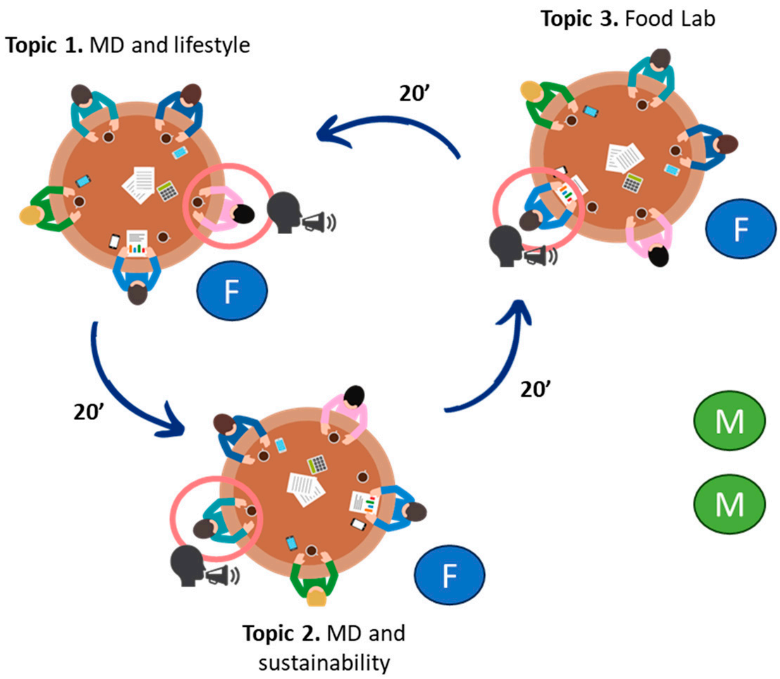

Figure 3. Codesign of educational activities: World Café Methodology.

During Phase 2 (month 10 to month 13), the codesigned activities will be carried out by adolescents at home (or in other nearby places, like markets) together with family and at research facilities together with the research staff. Four activities will be carried out on each selected topic in each month of intervention. Adolescents will be provided with a practical support handbook (or e-book) collecting all the activities and needed materials, which will be available and downloadable in different languages from the study website. Each activity will be described in the form of a didactic programing unit structured with the following sections: title, purpose, learning outcomes, preparation time and duration, methodology, materials required, and other resources. Due to the nature of this study, to avoid confounders in different intervention groups, these activities cannot be performed at school during the intervention. Nevertheless, the activity practical support handbook will be available for schoolteachers at the end of the intervention.

2.3.3. Healthy Plant-Based Snacks

The healthy and sustainable plant-based snacks will be developed and produced during Phase 1 of this study by three food companies located in Spain (DELAFRUIT S.L.U., Tarragona), Morocco (ECOMAB SARL, Casablanca), and Turkey (KOCAHAN SEKERLEME, Bursa) and will be consumed during the 3-month intervention by children aged 3 to 11 years.

The composition of the new food products will be based on local and traditional vegetables, fruits, legumes, seeds, and nuts as main ingredients, which are rich in health-promoting bioactive compounds. Processing and preservation strategies will be adapted to retain the nutritional value of the ingredients, and an eco-design methodology will be followed to produce the snacks [40]. In addition, the selection of the ingredients will be carried out beforehand in the three study countries through participatory focus groups involving parents and children. The locally produced plant-based ingredients will be presented to the families to determine their level of knowledge of them and the degree of incorporation in their diets (Table 2). The results of the focus group will allow the food manufacturers to reach a better understanding of the fruits, nuts, and vegetables the children usually consume in each country. Finally, after the preindustrial scale-up, four different snack prototypes to be used during the intervention in each country will be chosen according to the family's preferences, and the portions and frequency of consumption will be defined to complement the children's mid-morning and mid-afternoon snack, considering their nutritional and energy needs.

Table 2. List of ingredients presented to the families in the focus groups for each country.

Country	**List of Selected Ingredients**			
	Vegetables	**Fruits**	**Dried Fruits and Nuts**	**Legumes and Cereals**
Spain	Pumpkin	Mandarin Grape Peach	Almond	Chickpea
	Spinach	Nopal		Rice
	Sweet potato	Sumac	Walnut Hazelnut	Grains
Turkey		Jujube	Dates Dried apricot Almond	Chickpea powder
	Chicory	Black fig	Walnut	
	Black carrot	Black mulberry Blueberry	Hazelnut	Oatmeal

Table 2. *Cont.*

Country	List of Selected Ingredients			
	Vegetables	Fruits	Dried Fruits and Nuts	Legumes and Cereals
Morocco	Beetroot	Fig Orange Clementine Banana Apricot Apple Carob	Dates Almond Peanut Tigernut	Chickpea Whole wheat Oat

Since the snacks are produced with healthy and Mediterranean ingredients free of toxic agents and contaminants, no problems relating to children's safety are expected during the intervention study. At the time of family selection, the children's allergy history will be checked and the organoleptic characteristics of the snack products will be described to parents to verify the children's acceptance.

The snack products will be produced in a single batch in each country. Once produced, the manufacturers of each country will send them to the corresponding enrolment center prior to the start of the intervention study. The products will be delivered in a lot to the families in the same country at the beginning of the intervention.

2.4. Visits and Procedures

All families will attend the school facilities or at research centers where they are recruited on 3 different occasions (V0, V1, and V2). The visits will be divided between the two study phases previously described. Figure 4 shows the schedule of each visit, which will follow the same timeline for each enrollment center.

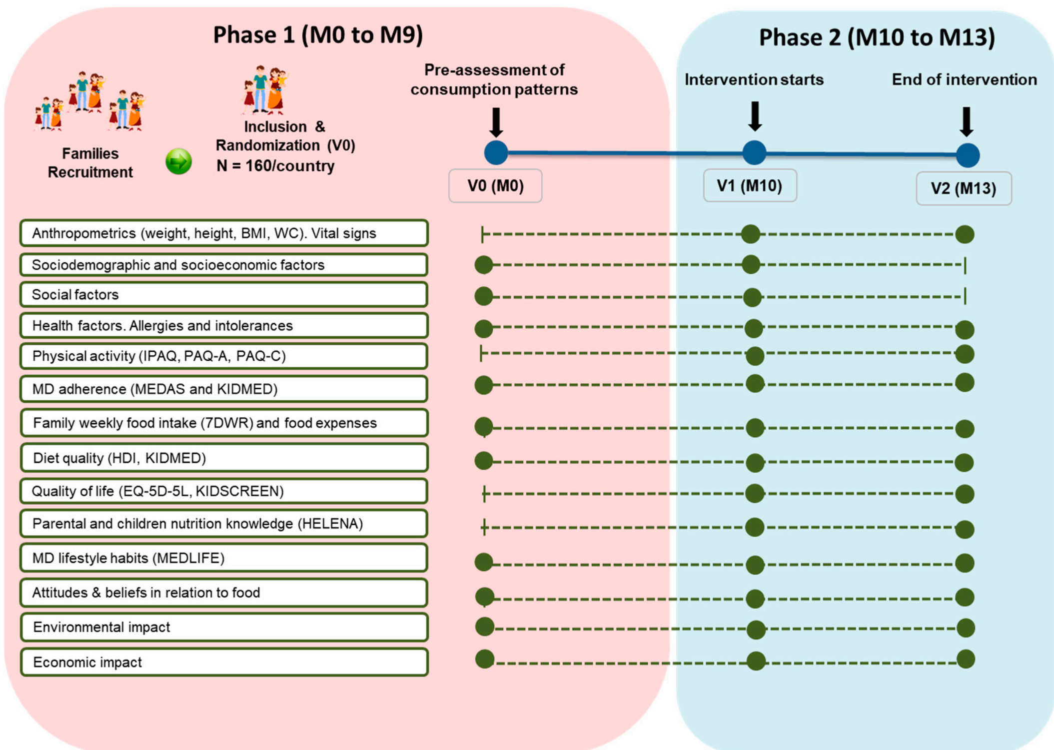

Figure 4. Description of study visits and outcomes.

In Phase 1, families will be recruited and a preassessment visit will be carried out (V0). At this point, families will be assessed against the eligibility criteria and then informed about this study in a group session. The informed consent document will be signed by parents and adolescents. The researchers will then instruct them on the completion of online questionnaires at home through the Microsoft Forms web-based application to assess socioeconomic, sociodemographic, lifestyle, and environmental indicators. This information will be valuable in predicting selected behavior sub-domains that will be evaluated based on a theoretical model derived from the COM-B model for behavior change. A theoretical model based on information on physical activity, food habits, lifestyle, and social behavior will be created, aiming to achieve the best outcomes via surveys that are not too long [41]. In addition, families will complete a 7-day semi-weighted food record (7DWR) to assess dietary habits and consumption patterns at baseline. After V0, the selected families will be randomly allocated to the different intervention/control groups.

In Phase 2, the selected families will attend V1 and V2 at the beginning and end of the 3-month intervention study, respectively. In V1, families will receive group training according to the different intervention groups: on the use of the S2H app, on snack consumption, and/or on the use of educational materials and activities. In addition, each family will be visited individually by expert nutritionists who will assess adherence to the MD through the MEDAS and KIDMED questionnaires for adults and children, respectively, and will take anthropometric measurements (body weight, height, BMI, waist circumference, blood pressure, and heart rate) for each family member. Nutritionists will also complete a medical history, including the use of medications and/or supplements. At the end of V1, time will be left for families to self-complete online questionnaires through the Microsoft Forms web-based application. The questionnaires will be adapted according to the age of the family members to assess socioeconomic, lifestyle, dietary, and environmental indicators. In addition, families will complete a 7DWR and report food expenses during the week after V1.

During the 3-month intervention, families will use the different educational components and products. They will be in continuous contact with the research team to ensure compliance and report any adverse events, particularly in children assigned to consume the snack products. In V2, each family will be visited individually, the same parameters as those in V1 will be measured by nutritionists, and data on socioeconomic, lifestyle, dietary, and environmental indicators will be self-reported by each family member by means of online questionnaires. A closing session of this study will be carried out by researchers once the intervention is completed to inform the families of the main results of the study.

2.5. Outcomes

The primary outcome will be adherence to the MD measured through the MEDAS and the KIDMED questionnaire score in parents and children, respectively. The MEDAS is an extension of a 9-point score developed in the Prevención con Dieta Mediterranea (PREDIMED) trial [42,43]. It consists of 2 questions about eating habits, 8 questions about the frequency of consumption of typical foods of the MD, and 4 questions about the consumption of foods not recommended in this diet. Each question is scored with 0 (non-compliant) or 1 (compliant), and the total score ranges from 0 to 14, so a score of 14 points means maximum adherence. The KIDMED score consists of 16 items with affirmative or negative answers, where there are 4 questions denoting a negative connotation to the MD and 12 questions denoting a positive connotation. A positive answer to questions denoting negative connotation is scored with -1, while positive connotation questions are scored with +1. The total score ranges from 0 to 12, so a score of 12 points indicates good adherence [44]. To avoid deviations in outcomes (such as physical activity or portions of food), surveys will be assessed by researchers during visits.

The secondary outcomes will include the following:

1. Anthropometric data: body weight, measured in all family members with a Tanita DC 430S-MA (Tanita Corp., Barcelona, Spain); height, obtained using a wall-mounted

stadiometer (Tanita Leicester Portable; Tanita Corp., Barcelona, Spain); waist circumference, measured at the level of the narrowest region between the last costal (10th rib) and the edge of the iliac crest using a 200 cm anthropometric steel measuring tape; and BMI, obtained using the formula of weight in kilograms divided by the square of the height in meters.

2. Systolic and diastolic blood pressure and resting heart rate, measured twice at 1 min intervals using an automatic sphygmomanometer (OMRON HEM-907; Peroxfarma, Barcelona, Spain).
3. Sociodemographic and socioeconomic factors, measured in parents and adolescents via an adapted questionnaire from Rodríguez-Rodríguez et al. [45]. This questionnaire will collect information regarding age, gender, household members, marital status, income, level of education, and employment status.
4. Social factors, measured in all family members via an adapted questionnaire from McIntosh et al. [46]. This questionnaire will collect information regarding work flexibility and satisfaction, work–life balance, lifestyle, time spent with children, family decision making, and task responsibility.
5. Physical activity, measured in all family members by validated physical activity questionnaires, IPAQ for adults [47] and PAQ-C [48] and PAQ-A [49] for children aged over 8 years and adolescents, respectively.
6. Health factors, measured in all family members via the General Health Questionnaire (GHQ) [50]. This questionnaire will ask about different aspects related to health and healthy lifestyle such as sleeping habits, hospitalization, and prescribed medications.
7. Mediterranean lifestyle habits, measured only in parents via the Mediterranean Lifestyle index (MEDLIFE), which will capture adherence to an overall Mediterranean healthy lifestyle [51].
8. Diet quality, measured via the Healthy Diet Index (HDI) [52] for adults and KIDMED [44] for adolescents and children.
9. Quality of life, measured via the EQ-5D-5L scale for adults [53] and the KIDSCREEN scale for adolescents and children aged over 8 years [54]. The EQ-5D-5L assesses five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The KIDSCREEN assesses children's and adolescents' subjective health and well-being.
10. Nutritional knowledge, measured via a short consumer-oriented nutrition knowledge questionnaire for adults [55] and the HELENA questionnaire for adolescents, which also includes a self-reported food frequency questionnaire [56]. These questionnaires will measure the parents' and adolescents' knowledge of a healthy diet.
11. Attitudes and beliefs in relation to food, measured via an adaptation of the McIntosh et al. questionnaire [46] and the Early Parenting Attitudes Questionnaire (EPAQ) [57]. These questionnaires will assess the family eating habits and attitudes of and barriers faced by parents and adolescents in relation to the MD.
12. Family weekly food intake, measured in all family members via a 7DWR, which involves an individual weighing of each food item prior to consumption. The 7DWR will be completed during the week after visit V0 and V1 and the week prior to visit V2. In V0, families will receive instructions for the correct completion. Nutritionists will instruct families on the use of kitchen scales. Apart from food, 7DWR will allow data on the average intake of macro- and micronutrients to be obtained.
13. Family weekly food expenses, measured per family unit using shopping receipts collected during the week after visit V0 and V1 and in the week prior to visit V2. In each visit, families will be provided with an envelope for collecting the shopping receipts and other food expenses for a week.
14. Environmental impact of food consumption, assessed by converting the 7DWR consumption quantities into kg of CO_2 emission, land use, and water footprint using existing data in the literature on the environmental impacts of different food groups [58–60].

15. Economic impact, estimated using the data obtained from family weekly food records and expenses reported by means of shopping receipts. Two measurements will be carried out at the beginning and end of the 3-month intervention, and potential effects of promotions at the specific retail outlet as well as family events and the seasonal effect will be controlled.

Each specific outcome and visit are summarized in Figure 4.

The integrated data from the primary and secondary outcomes, including MD adherence, diet quality, family weekly food intake, and food expenses, will provide an overview of the three main impact dimensions: quality of diet and health, economic, and environmental. These indicators will allow us to better understand the reasons behind dietary behavioral changes to facilitate the scaling-up of the most effective interventions or to redesign the less effective ones in the future.

2.6. Randomization and Allocation

After the baseline preassessment visit (V0), participating families will be randomized into the eight study groups. The randomization sequence list will be generated using the Randomization.com website (http://www.randomization.com) (accessed on 13 September 2024) by an external researcher not involved in this study. Stratified randomization, employing blocking, will be conducted to achieve a 1:1:1:1:1:1:1:1 ratio for the 7 intervention groups and the control group; $n = 60$ families per block. Due to the nature of the study, the families and the research staff cannot be blinded to the intervention, although the investigators who will perform the data analysis will work under concealment of the assignment.

2.7. Sample Size

The sample size was calculated based on differences in MD adherence score (primary outcome) measured by MEDAS and KIDMED questionnaires. The sample size was estimated using the analysis of variance (differences between 8 study groups). It was assumed that the alpha value would be equal to 0.05 and beta 0.20, exactly as reported in previous studies [61], with a common standard deviation equal to 1.19. The minimum group size needed to detect a minimum increase of 1 point in the intervention group's MEDAS compared to the control group is equal to 45 families per study group (15 families per country). The total sample is, therefore, $45 \times 8 = 360$ families. However, assuming a 25% drop-out rate, the minimum group size is equal to 60 families per study group (20 families per country). Overall, 160 families will thus be recruited per country after obtaining the approval of the Ethics Committee of each recruiting center and written informed consent from parents and adolescents.

2.8. Criteria for Discontinuing or Modifying Allocated Intervention

If a severe or unanticipated adverse event (AE) occurs that may influence the risk/benefit ratio of this study, the principal investigator must report this to the ethics committee and permanently discontinue the family from the intervention. Participating families will be asked to report any AEs experienced during the entire intervention. For each AE, the onset date, intensity, relationship to the study product, action taken, and outcome will be recorded by researchers in accordance with the Medical Dictionary for Regulatory Activities (MedDra dictionary), Version 24.0 of MedDRA (Spanish), March 2021. In case of the suspicion of a major AE, such as an allergic reaction, the case will be referred directly to the study doctor, who will evaluate the symptoms and signs and adopt the necessary measures according to their severity.

In addition, the researchers can withdraw a family from this study if they consider that the family can no longer meet all the requirements of the study or if any of the procedures are considered possibly harmful for any of its members. Families participating in the study will be withdrawn if they meet any of the following criteria: (1) any circumstance that prevents them from performing the study procedures (i.e., using the educational materials or digital interactive tools and complying with the intake of the study products); (2) not attending study visits.

The losses and dropouts will be carefully recorded to ensure study reliability. The next participant who meets the eligibility criteria will replace the last participant who withdraws from the research until reaching the calculated sample size.

2.9. Data Management

All data will be collected and evaluated by experienced researchers and registered by the same researchers or study participants through predesigned forms in the Microsoft Forms web-based application.

The online forms will be self-completed by families at home in V0 and at the research center or school facilities in V1 and V2 with the assistance of the research staff. The forms will be adapted from validated scales for adults, adolescents, and children, and translated into the language of each country (Spanish, Turkish, French, and Arabic). They will comprise nine blocks of questions assessing various factors of interest (attitudes, intentions, self-efficacy, time allocation, work and household stress, health, nutrition, etc.), all of them integrated using a theoretical framework matrix [46,55,62] (Table 3).

Table 3. Blocks of questions in the online forms for families.

Block	Assessed Factors
Socioeconomic factors	Age, gender, ethnicity, household members, marital status, income, level of education, and employment status
Social factors	Work flexibility and satisfaction, work–life balance, lifestyle, time spent with children, family decision making, and task responsibility
Psychological factors	Self-perception
Quality of life	Mobility, self-care, usual activities, pain/discomfort, anxiety/depression, and subjective well-being
Attitudes and beliefs related to food	Family eating habits and attitudes of and barriers faced by parents and adolescents related to the MD
Health and healthy lifestyle	Smoking, hospitalization, medication use, and sleep duration
Dietary habits	Eating rules, amount and type of food consumed, and food frequency intake
Nutritional knowledge	Level of knowledge of parents and adolescents on a healthy diet
Physical activity	Types and intensity of physical activity and sitting time spent as part of the individual's daily life

Each family will be provided access to the Microsoft Forms links with a unique code previously assigned. Each member of the family must complete their own forms, except for children under 8 years of age, who will need the help of their parents for completion. In total, parents must complete 3 forms, adolescents 2 forms, and children under 12 years of age only 1 form. The average time for parents to complete the forms is 40 min, while it will only take about 20 min for adolescents and children under 12 years.

Anthropometric measurements will be collected at V1 and V2 by trained nutritionists with specific devices and registered in an online data collection notebook available for each family member in the Microsoft Forms web-based application.

Data on consumption patterns will be recorded in writing format in a notebook including a 7DWR. For one week, families must record all the foods and drinks and the amount consumed for each member of the family. In addition, they will have to record food expenses and keep shopping receipts. The researchers will check the data provided and transfer them to a common Excel database for the three enrolled countries to assess the economic and environmental impact.

Data generated with Microsoft Forms will be exported to Microsoft Excel. Access to the database will be restricted only to authorized personnel of the research team. All participant data will be hosted by the responsible researcher in protected folders in the cloud of the institutional Microsoft OneDrive server located in the European Economic Area to guarantee privacy.

2.10. Statistical Analysis

2.10.1. Univariate Data Analysis

The data obtained from families in this study will be evaluated via an intention-to-treat (ITT) analysis, including data from families who drop out of the study, and per protocol (PP), that is, those families who have completed the treatment plan and who have exactly followed the instructions of the trial protocol. The error level of 0.05 will be set as a limit of statistical significance. A data analysis will be performed using the Statistical Software for Data Science (STATA, College Station, TX, USA) version 17.0 [63].

Mean and standard deviation will be reported for normally distributed variables and quantiles (25th percentile, median, and 75th percentile) for non-normally distributed variables. The Kolmogorov–Smirnov test and the Shapiro–Wilk test will be used to test for the normality of variables. The resulting scores of adherence to the MD (measured from the MEDAS and KIDMED questionnaires) will be used to calculate the mean differences between each intervention group and the control group before (V1) and after interventions (V2). Multiple comparisons (V2 vs. V0 and V2 vs. V1) of mean differences before and after interventions will be undertaken to assess the independent effect of interventions. The normality of the differences will be checked and, depending on the results, the following contrasts will be performed: parametric statistics (three-factor ANOVA with post hoc tests using the Bonferroni correction and considering the interactions between the following factors: app, educational materials, and snack products) will be used for normally distributed variables to compare differences in means and nonparametric statistics (Kruskal–Wallis test) will be used for non-normally distributed variables. Lineal regression and Spearman's method will be used to test for correlations between normal and non-normal outcome variables, respectively.

2.10.2. Multivariate Data Analysis

Structural equation modeling (SEM) is a multivariate, hypothesis-driven technique that is based on a structural model representing a hypothesis about the causal relations among several variables. It will integrate the multiple factors affecting the adherence to the MD, including economic factors, social factors, psychological factors, quality of life, attitudes and beliefs related to food, health and healthy lifestyle, dietary habits, nutritional knowledge, and physical activity. It will test the direct and indirect effects of these multiple factors on the adherence to the MD. Fit indices like the root mean square error of approximation (RMSEA), the Tucker–Lewis index (TLI), and the comparative fit index (CFI) will be used to check for the adequacy of the fit of the model.

We will monitor model fit indices (RMSEA, TLI, and CFI) to ensure they fall within acceptable ranges and adjust the SEM model structure as necessary based on theoretical and statistical considerations to maintain interpretability. Missing data will be handled using Full Information Maximum Likelihood (FIML) estimation, an approach suited to SEM that reduces bias by using all available data without directly imputing values. Additionally, we will evaluate patterns of missingness to determine if data are missing at random (MAR) or missing not at random (MNAR) and will justify our handling approach accordingly. The reliability will be checked using three criteria, including the internal consistency, composed reliability, and average variance extracted (AVE). Cronbach's alpha coefficient will be used to test the internal consistency of the scales. For validity, two criteria will be tested, including the convergent validity and the discriminant validity [62].

To address the socioeconomic and cultural differences among participants from Spain, Turkey, and Morocco, a stratified analysis will be conducted to examine the impact of socioeconomic and cultural contexts on participants' responses to the interventions. By categorizing participants based on key demographic variables such as income, education level, and cultural background, we can gain insights into how these factors influence dietary behaviors and adherence to the MD.

3. Discussion

The long-term feasibility of nutrition education programs is limited at the family level, so it has been suggested to use complementary nutrition interventions to build a supportive environment for effective healthy eating in the family setting [28]. To the best of our knowledge, the SWITCHtoHEALTHY study is the first multicentric nutritional intervention study assessing the effectiveness of a multi-component intervention to improve the adherence of Mediterranean families to the MD eating pattern through sustained changes in dietary behavior.

The novelty of the SWITCHtoHEALTHY study relies on the holistic family-based approach that combines and adapts different interactive tools, snack products, and methodologies designed to foster adherence to the MD of the different family members (parents, adolescents, and children) by considering their specific needs. The proposed approach involves the four main driving forces that, together, improve adherence to the MD eating pattern: sociocultural, economic, environmental, and health–nutritional [64].

Despite its well-known benefits, the MD is being abandoned or not adopted by young generations in most Mediterranean countries. The erosion of the MD dietary pattern in the modern era came with globalization, since it is often cheaper to import food from abroad than making local food available. Together with this, the increase in the consumption of ultra-processed food, food insecurity, and youth unemployment are all predisposing factors to unhealthy eating behavior [4,13]. In Spain, up to 69% of the child and adolescent population has been found to have suboptimal adherence to the MD according to the KIDMED index. The prevalence of low adherence is higher for secondary school than for primary school children [65,66]. In Moroccan and Turkish populations, only about 15% of adolescents have optimal adherence to the MD; among the factors associated with greater adherence, female gender, high monthly family income, and living in an apartment stand out [67–69]. In the same way, adolescents and young people living in Europe are far from being compliant with the nutritional recommendations for fruit, vegetables, legumes, and sodium, and they do not follow the principles of the MD [70,71]. Some factors positively associated with an optimal adherence to the MD are the mother's education level, the absence of distractions at breakfast, and regular physical activity, all factors that depend largely on the family environment [66].

Recently, healthy lifestyle-based interventions have been shown to be effective in increasing adherence to the MD and in achieving optimal adherence to this dietary pattern among children and adolescents [25,72]. According to a recent meta-analysis, greater improvements in achieving optimal adherence to the MD are found in interventions delivered out of school, those aimed at both children and parents, and those including participants with overweight/obesity [25]. The SWITCHtoHEALTHY intervention will adopt a "treat the family" approach to strengthen the adherence to the MD, focusing on the families and particularly families with children (kids and adolescents) for two main reasons: firstly, meals are one of the most important social activities among family members and one of the essences of the MD that is currently being abandoned; secondly, children's food habits are primarily acquired within families, and some of these food habits will persist over time. Families will be the unit of analysis as we try to understand the environmental factors affecting food consumption. Ultimately, this study aims to promote the MD by empowering families to be the actors of such behavioral change, generated from and for the family setting. This is a novelty when compared to other individual-driven interventions focused on specific age targets.

The use of the S2H app will support parents in preparing healthier weekly dietary plans, which will lead to greater adherence to the MD of the entire family. According to prior studies, technology-based interventions delivered via smartphone apps are successful in helping individuals achieve better improvements towards MD adherence in the short term [73] and have shown satisfactory usability, especially among young people [74]. Given the widespread use of digital devices, the potential of smartphone use in low- and middle-income countries has already been highlighted in the literature [75,76]. mHealth has been reported in the literature as a widely used tool to improve health outcomes for vulnerable communities in developing countries worldwide, such as those in Africa, Asia, and Latin America. The importance of implementing these methodologies according to the sociocultural needs of each population group is reiterated in the SWITCHtoHEALTHY project. The app developed within the project is based on the findings of a preliminary phase of research into the habits and needs of each individual country involved in this study. It also addresses this challenge by providing meal plans based on the MD, aligned with the cultural traditions of each participating country.

On the other hand, the development of novel healthy snack products has the potential to improve the contribution of essential nutrients in children's diets and, in the longer term, may reduce the impact of poor nutrition on public health [77]. Snacks are generally eaten between main meals, often with the intention of reducing or preventing hunger until the next meal. Healthy food options, such as fruits, nuts, and vegetables, should be promoted as between-meal snacks to avoid the consumption of energy-dense and processed foods like chips, biscuits, and sweets [78]. In this context, the SWITCHtoHEALTHY plant-based snacks will be made with a variety of local fruits, vegetables, legumes, and nuts to cover the nutritional needs of children in the mid-morning and mid-afternoon periods. It should be noted that the ingredients used for its preparation will be easily accessible in each country and can even be prepared in a similar way at home by families in the long term, for example, in the form of blends, purees, and bars.

The main strengths of this study are the multicentric nature of the intervention and the transferability and scalability of the educational materials designed in the frame of the project to be reproduced and replicated in other environments and countries beyond the project boundaries (e.g., workplaces, schools, campus canteens, and restaurants). During the intervention, the educational materials will be used at the family level to educate families on the MD and associated health benefits through a toolkit that combines information and tips to cook, prepare foods, benefits, and culture behind MD. In addition, adolescents will conduct educational activities codesigned with them that will reinforce their healthy dietary habits. Once the intervention ends, the materials could be used at the school level, serving as educational resources for teachers to become food educators. In fact, previous studies have shown the effectiveness of nutritional interventions led by trained teachers on improving adherence to the MD in schoolchildren, e.g., The Nutrition Education Teaching Pack (TP) funded by the Italian Ministry of Agricultural, Food, and Forestry Policies [79]. However, the adaptability of the materials is not exempt from challenges, especially when talking about populations outside the Mediterranean region. Materials may need adaptation to account for social and cultural differences. Local language translations would be essential to ensure accessibility and comprehension for participants from different linguistic backgrounds. Finally, resource availability, both in terms of foods typical of the MD and the economic means to procure them, would need to be addressed in any region-specific adaptation, ensuring alignment with local capacities and constraints.

On the other hand, the SWITCHtoHEALTHY study will play a key role in the achievement of a large part of the sustainable development goals (SDGs) linked to EU policies [80]. This will be, to a greater extent, possible through actions such as the transference of knowledge and skills for sustainable development; the valorization of food products from the traditional MD by using local plant varieties and eco-friendly food processing technologies; and the reduction in global food waste and the carbon footprint by promoting a sustainable consumption. In addition, it is expected that the intervention enhances food security and nutrition by providing personalized meal plans, improving diet quality indexes for at least 75% of participants.

Some potential limitations need to be considered. First, given that the dietary habits of children under 8 years of age will be answered by parents, it can suppose an underestimation or overestimation of the consumption of certain MD food groups, so the results could be biased. Second, the differences in socioeconomic and cultural factors among participating families could influence the changes in dietary habits given that certain typical

MD foods such as virgin olive oil may not be accessible to families with lower incomes. To account for this, our approach incorporates data collection on household income and food expenditure through structured questionnaires. This will allow us to analyze how financial factors impact dietary choices and adapt our strategies to accommodate families' economic realities. In addition, the fact that the interventions will take place in three different cultural areas could bias the results given different culinary traditions and beliefs around Mediterranean foods. Despite this, a tailored approach will be used for the design of menus and educational materials adapted to country specificities. Third, due to the nature of the interventions, participants and researchers cannot be blinded, although researchers who will perform the statistical analyses will be. Fourth, the gap in time between V0 and the start of the intervention (V1) can lead to a high drop-out rate of families. Another limitation is the use of the family as a unit of analysis, which means that all members must be involved and willing to lead the intervention to achieve change. Additionally, the short intervention period (3 months) might limit conclusions on the long-term effects. The three-month timeframe was chosen due to the limited duration of the project and the long time needed for the design of the study and the intervention components. This short-term assessment provides a foundation for understanding the intervention's immediate effectiveness and establishes groundwork for future studies to explore the long-term sustainability of MD adherence. Finally, families could experience a loss of adherence to the intervention components, particularly to the use of the app. The use of eHealth tools presupposes that users have a certain level of skills and competence (eHealth literacy) [81]. In this sense, the S2H app will be user-friendly and universally accessible, and it will have a usability monitoring system.

Regarding the long-term adoption of healthy eating habits at the family level through multi-component interventions such as those proposed in this study, it is worth considering some barriers that may hinder adherence to interventions such as antisocial behavior during adolescence or the lack of parental engagement due to lack of time. For this reason, family-based interventions may focus on the provision of skills, knowledge, and support; frequency and quality of parent–child communications; and reinforcement of shared values and behaviors ensuring the involvement of all family members [17]. The holistic family-based approach planned for the SWITCHtoHEALTHY study will consider all these barriers associated with family behavior. Furthermore, the use of development methodologies such as the learning-through-playing approach will encourage children and adolescents to develop cognitive and communication skills, learn to manage their emotional states, and gain self-confidence for changing their eating behaviors [82].

While this study focuses on promoting adherence to the core components of the MD, such as the increased consumption of fruits, vegetables, whole grains, legumes, and extra virgin olive oil, we acknowledge the recent shifts in dietary habits in Mediterranean countries. The rising intake of ultra-processed foods and the use of oils other than extra virgin olive oil are noteworthy trends that may influence adherence to traditional dietary patterns.

The multidisciplinary consortium will facilitate the exchange of best practices among Mediterranean basin countries to create common knowledge and understanding on the impact of greater adherence to the MD at the health, environmental, and economic level. It will facilitate generating, boosting, and maintaining the switch to a healthier Mediterranean dietary pattern across the Mediterranean area. The key findings generated will be translated into the development of new future strategies to increase the adaptation of individuals to the MD by encouraging nutritionally adequate, healthy, and sustainable behaviors [83]. The results will be summarized, and recommendations will be prepared for government bodies, public health institutions, and NGOs across the Mediterranean. These documents will translate scientific results into actionable policies. In addition, a series of workshops and roundtables will be organized in collaboration with national health ministries and local authorities in Spain, Morocco, and Turkey. The most impactful components (e.g., plant-based snacks and digital tools) will be proposed for inclusion in national and regional health programs, with the support of cost–benefit analyses demonstrating their scalability and sustainability. By employing these mechanisms, SWITCHtoHEALTHY aims to ensure that its findings do not remain confined to the academic sphere but are translated into practical strategies adopted by policymakers and public health institutions across the Mediterranean region.

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Institutional Review Board Statement: This study will be conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Institut d'Investigació Sanitària Pere i Virgili, IISPV (Ref. 135/2023; 27 June 2023), Ethics Committee of Bursa Uludag University Faculty of Medicine Clinical Researches (Ref. 2023-23/29; 7 November 2023), and Comité d'Ethique pour la Recherche Biomédicale (CERB), Université Mohammed V Faculté de Médecine et de Pharmacie de Rabat (preapproval).

Informed Consent Statement: Informed consent will be obtained from all subjects involved in this study.

Data Availability Statement: Data will be made available upon reasonable request.

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Dietary patterns of university students in the UK: a cross-sectional study

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Abstract

Background: University represents a key transition into adulthood for many adolescents but there are associated concerns about health and behaviours. One important aspect relates to diet and there is emerging evidence that university students may consume poor quality diets, with potential implications for body weight and long-term health. This research aimed to characterise dietary patterns of university students in the UK and their sociodemographic and lifestyle antecedents.

Methods: An online, cross-sectional survey was undertaken with a convenience sample of 1448 university students from five UK universities (King's College London, Universities of St Andrews, Southampton and Sheffield, and Ulster University). The survey comprised a validated food frequency questionnaire alongside lifestyle and sociodemographic questions. Dietary patterns were generated from food frequency intake data using principal components analysis. Nutrient intakes were estimated to characterise the nutrient profile of each dietary pattern. Associations with sociodemographic variables were assessed through general linear modelling.

Results: Dietary analyses revealed four major dietary patterns: 'vegetarian'; 'snacking'; 'health-conscious'; and 'convenience, red meat & alcohol'. The 'health-conscious' pattern had the most favourable micronutrient profile. Students' gender, age, year of study, geographical location and cooking ability were associated with differences in pattern behaviour. Female students favoured the 'vegetarian' pattern, whilst male students preferred the 'convenience, red meat & alcohol' pattern. Less healthful dietary patterns were positively associated with lifestyle risk factors such as smoking, low physical activity and take-away consumption. The health-conscious pattern had greatest nutrient density. The 'convenience, red meat & alcohol' pattern was associated with higher weekly food spending; this pattern was also identified most consistently across universities. Students reporting greater cooking ability tended towards the 'vegetarian' and 'health-conscious' patterns.

Conclusions: Food intake varied amongst university students. A substantial proportion of students followed health-promoting diets, which had good nutrient profiles obviating a need for dietary intervention. However, some students consumed poor diets, incurred greater food costs and practised unfavourable lifestyle behaviours, which may have long-term health effects. University policy to improve students' diets should incorporate efforts to promote student engagement in cooking and food preparation, and increased availability of low cost healthier food items.

Keywords: Food consumption, Principal components analysis, Survey, University students

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Background

University students represent a substantial proportion (50%) of the UK young adult population [1] and an individual's university career may be influential in the establishment of long-term eating patterns and thus chronic disease risk. This population also represents a group of young adults with a set of unique factors driving dietary intake: the transition to university life may be associated with increased autonomy over food choice, small food budgets, and exposure to new social groups and food cultures.

A limited body of data indicates that the dietary behaviours of UK university students are not conducive to either short- or long-term health. Alcohol consumption has received most research attention revealing that binge drinking is endemic [2, 3]. There are also indications of high intakes of confectionery and fast foods, and low consumption of fruit and vegetables [3, 4]. Although there is some evidence that dietary behaviours track from adolescence to adulthood [5, 6], the transition from home to university life has been associated with unfavourable changes to food intake: increases in alcohol and sugar intake, and decreases in fruit and vegetable consumption have been reported [7].

Additionally, the first year of university life has been identified as a period associated with body weight gain in both North American [8] and UK students [9, 10]. Such weight gain may have long-term repercussions, since overweight during young adulthood has been identified as a significant predictor of obesity later in life [11]. Furthermore, high rates of body dissatisfaction and dieting behaviours have been noted, particularly amongst female students [12, 13]. Such engagement in dieting behaviour and dysfunctional relationships with food not only impact on dietary adequacy [14, 15], but may also create tension and conflict for young people as they develop relationships with new peer groups [16].

Dietary studies of British university students are constrained by crude dietary assessment, small sample size and generally focus on a single university [3, 4]. Furthermore, their analytical approach has been on single foods and/or nutrients, which has allowed assessment of intake relative to dietary recommendations. Using multivariate statistical techniques to identify dietary patterns through intake of multiple interrelated food groups captures the complexity and multidimensional nature of diet, which is representative of real life food consumption [17]. This approach also allows greater insight into the different patterns of food consumption that naturally occur within a population and facilitates identification of sub-groups who may be most in need of health promotion efforts. Universities in particular may represent a setting in which dietary behaviours are open to change and large groups of young adults can be reached, representing an appropriate target for health promotion efforts. A dietary patterns approach has been used widely in various UK population groups, but has not been employed to characterise the diets of university students.

This study aimed to identify dietary patterns that exist within a UK university student population, to assess the nutritional profile of these patterns, and to examine socio-demographic and lifestyle variables underpinning these patterns.

Methods

Study design

This cross-sectional study involved a convenience sample of five regionally and socio-economically diverse universities throughout the UK (Universities of: Sheffield, Ulster, King's College London (KCL), Southampton and St Andrews). These universities had responded positively to an invitation to participate in the research study; contact was made via university Human Nutrition or Health Sciences departments. A web-survey, comprising a validated food frequency questionnaire (FFQ) (Tinuviel Software Ltd., Warrington, UK) was used to assess dietary intake. Socio-demographic and lifestyle data were also collected. The survey was conducted between Autumn 2013 and Spring 2015. Data collection was preceded by a pilot study, which was used to refine the web-survey.

Ethical approval was obtained from each participating university. Informed consent for participation was obtained on the first page of the web-survey.

Subjects & recruitment

All British and European Union students less than 30 years of age at the five participating universities represented eligible participants. A cut-off of 30 years was chosen in order to focus on the dietary behaviours of young adults. International students (non-Home or non-EU) were not included because of possible heterogeneity in food choice (this issue was identified in the pilot study), and the dietary assessment instrument used was Euro-centric. Students identifying as international students on the first page of the online survey could not proceed. Only health sciences students were recruited at the University of Southampton, because of logistical issues in distribution of the survey. All students were recruited through university email distribution lists. This email provided study details and emphasised that students did not have to be eating a healthy diet to participate. Participants were required to recall their habitual diet over the most recent university semester (three months). This was the autumn semester 2013 for students at Sheffield, the autumn semester 2014 for students at Ulster and KCL, and the spring semester 2014 for students at Southampton and St Andrews. Participants who provided their contact details were entered into a prize draw; each person could win one of 40 £20 high street vouchers.

Participant eligibility

A total of 1683 students across the five universities responded to the survey. Figure 1 shows numbers of students excluded based on fulfilment of various eligibility criteria. The cut-offs for implausible energy intakes in the Nurses' Health Study (< 500 Kcal/day and > 3500 Kcal/day) and Healthcare Professionals' Follow-up Study (< 800 Kcal/day or > 4200 Kcal/day) were used to identify and exclude participants reporting implausible energy intakes the current study. Using this method, 24 participants were identified as over-reporters (8 males; 16 females) and three participants were identified as under-reporters (1 male; 2 females). A total of 1448 students comprised the final sample.

Dietary data

A validated 111-item FFQ originally developed by the Medical Research Council was employed to assess dietary intake (DietQ; Tinuviel Software Ltd., Warrington, UK; [18, 19]. The FFQ was piloted among 40 students at the University of Sheffield. Feedback from the pilot study led to three further items being incorporated into the questionnaire (consumption of hummus; tofu; water).

Frequencies of consumption in the questionnaire were expressed as follows: every day = 7/week, through to once per week = 1/week; once every 2–3 weeks (F) = 0.5/week; rarely/never (R) = 0. Where absolute quantities of consumption were given, these were converted into number of portions consumed per day. Food and nutrient intakes were generated directly from these FFQ data using the nutritional analysis software QBuilder (Tinuviel Software, Warrington, UK). The original 111 foods/food groups listed in the FFQ were condensed into 55 broader foods/food groups for dietary patterns analysis. These 55 foods/food groups are detailed in Additional file 1: Table S1.

Socio-demographic, anthropometric and lifestyle data

The following socio-demographic information was collected: age; gender; degree programme and year of study; full/part-time study; nature of term-time residence; ethnicity; religion; socioeconomic status (SES); maternal education; and university attended. Information on dieting/weight loss behaviour, supplement use, cooking ability (four response options from 'able to cook wide range of meals from raw ingredients' through to 'unable to cook at all'), smoking status (students were asked to self-identify as a never smoker, ex-smoker, social smoker or regular smoker), self-reported physical activity levels (students were required to self-identify as not very active, moderately active or very active), body weight (kg) and height (m) (for calculation of body mass index (BMI), kg/m^2), cooking behaviours (consumption of: meals made from raw ingredients; pre-prepared foods; ready meals and take-aways; and meals from university cafeteria) and weekly food expenditure (£) was also collected.

Identification of dietary patterns

To generate dietary patterns, the 55 food/food group intake variables were entered into a principal component analysis (PCA) and a varimax (orthogonal) rotation was performed. The number of components retained was determined by the scree plot, parallel analysis and component interpretability [20]. Food/food groups with factor loadings > 0.32 were used to interpret each dietary pattern.

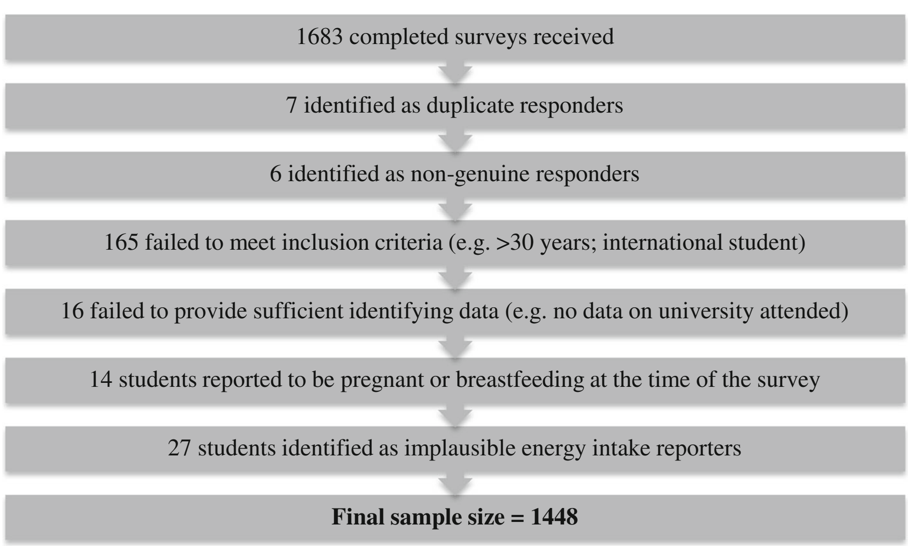

Fig. 1 Numbers of students excluded based on fulfilment of various eligibility criteria

Statistical analysis

Pearson's product moment correlation coefficients were calculated between pattern scores and absolute nutrient intakes. Partial correlation coefficients were also calculated, which adjusted for energy intake. Correlation coefficients ≥0.5 and ≤ − 0.5 were considered strong. Examination of scatter plots revealed no evidence of non-linear relationships between component scores and nutrient intakes.

General linear models (GLMs) were firstly fitted for demographic variables alone (model 1) and then with additional eating factors (model 2). Maternal education was not included in the models, since data were not available for all students. Religion was also not included due to confounding with ethnic background.

Variables were categorised into two groups for entry into a GLM: 1) demographic variables: gender, age, leisure-time physical activity, BMI, smoking, ethnicity, year of study, term-time accommodation, university attended, and full-time/part-time status 2) cooking- and eating-related variables: cooking ability, animal food consumption, frequency of consumption of meals prepared using raw ingredients, frequency of consumption of meals using pre-prepared foods, frequency of consumption of ready-meals and take-aways, frequency of consumption of meals from university cafeteria, frequency of skipping breakfast, frequency of skipping lunch, and amount spent on food.

For each retained dietary component a GLM was fitted with demographic variables only (Group 1). A second GLM was then fitted, which included significant demographic variables and variables from Group 2. Multi-comparison post-hoc tests with Sidak correction were carried out to aid interpretation of significant factors in the GLM. The Statistical Package for the Social Sciences (SPSS) Version 20 was used for all statistical analyses. A p value of < 0.05 was considered significant.

Results

Participant characteristics

The sociodemographic characteristics of the sample are shown in Table 1. The sample comprised 1064 (73.5%) women and 384 (26.5%) men. The majority of students were White British (n = 911; 62.9%) and registered for full-time study (n = 1394; 96.3%). The mean age of the sample was 21.5 years (SD 2.63 years). The majority of respondents were from the University of Sheffield (n = 567; 39.2%), Ulster University in Northern Ireland (n = 443; 30.6%) and KCL (n = 305; 21.1%). The remaining students were from the Universities of Southampton (n = 79; 5.5%) and St Andrews, Scotland (n = 54; 3.7%). Just over one-third of students were studying a health-related degree. The majority of students (n = 1000; 69.1%) reported a healthy BMI (18.5–24.99 kg/m^2); mean BMI was 22.8 kg/m^2 (SD 4.64 kg/m^2).

In terms of eating behaviours of the sample, just under two-thirds of students described themselves as regular meat-eaters, whilst approximately 10% of students identified themselves as vegetarian. Just over half (55%) of students reported that they were able to cook a wide range of meals from raw ingredients, and 73% consumed self-cooked meals from raw ingredients 'every' or 'most' days. One in four students reported that they consumed meals cooked from pre-prepared foods, which could be assumed to represent convenience foods, 'most days' or 'everyday'. Approximately 30% of students reported that they skipped breakfast at least most days. Just less than one quarter of students spent less than £20 on food each week; a weekly food budget of £20–29 was most common. Almost one in five students spent over £40 on food each week. Full details are provided in tabular form in Additional file 1: Table S2).

Dietary patterns

Four principal components were retained, which explained 21.7% of the total variance in food intake. The first component explained 8.4% variance; the three remaining components explained 5.7%, 4.2% and 3.4% of the variance in food intake respectively. Table 2 shows the factor loadings of each of the food groups in the four dietary components retained.

The first dietary component had high positive factor loadings (≥ 0.32) for pulses, beans and lentils, tofu, meat alternatives, hummus, nuts, and other green vegetables and salad items. It had high negative factor loadings for poultry, processed meat, and red meat and offal. This dietary pattern was labelled 'vegetarian', because there was a clear tendency towards consumption of non-meat protein sources and avoidance of all meat and fish products. The second dietary component had high positive factor loadings for biscuits, cakes and sweet pastries, milk- and cream-based desserts, confectionery, crisps and savoury snacks, fruit juice, other bread, pizza and fizzy drinks. This component was labelled 'snacking', because it was mainly characterised by snack-type foods that generally did not represent components of main meals, require no preparation and offered many options for mobile consumption. The third component had high positive factor loadings for fatty fish and canned tuna, white- and shellfish, nuts, eggs, fresh fruit, other green vegetables and salad items, oat- and bran-based breakfast cereals, herbal and green tea, and low fat/low calorie yogurts. This dietary pattern was labelled 'health-conscious', because it was characterised by foods typically associated with improved health, and was congruent with dietary components labelled 'health-conscious' or 'prudent' in other dietary pattern studies [21]. Finally, the

Table 1 Socio-demographic characteristics of the sample

	Number	Percentage (%)[a]
Gender		
Male	384	26.5
Female	1064	73.5
Age (years)		
17–21	873	60.3
22–25	412	28.5
26–30	163	11.3
BMI (kg.m^{-2})		
< 18.5	112	7.7
18.5–24.9	1000	69.1
25–29.9	220	15.2
≥30	76	5.2
Leisure-time physical activity		
Not very active	473	32.7
Moderately active	748	51.7
Very active	227	15.7
University attended		
University of Sheffield	567	39.2
Ulster University	443	30.6
KCL	305	21.1
University of Southampton	79	5.5
University of St Andrews	54	3.7
Faculty of study		
Arts	252	17.4
Social science	285	19.7
Engineering	109	7.5
Science	212	14.6
Medicine and health	521	36.0
Full or part time status		
Full time	1394	96.3
Part time	54	3.7
Year of study		
1st year undergraduate	489	33.8
2nd year undergraduate	301	20.8
3rd year undergraduate	264	18.2
4th or higher year undergraduate	136	9.4
Postgraduate	245	16.9
Other	13	0.9
Term-time residence		
University catered accommodation	58	4.0
University self-catered accommodation	340	23.5
Private accommodation with other friends/students	610	42.1
Private accommodation on own	63	4.4
With parents/relatives	205	14.2
With partner	107	7.4
With parents/partner & children	48	3.3
With children only	9	0.6
Other	8	0.6
Ethnic background		
White British	911	62.9
White Irish	235	16.2
Other White ethnicity	139	9.6
Mixed ethnicity	45	3.1
Asian/Asian British	69	4.8
Black/African/Caribbean/Black British	15	1.0
Other	16	1.1
Would rather not say	18	1.2
Mother's level of education		
CSE	80	5.5
Vocational	59	4.1
O Level	184	12.7
A Level	96	6.6
Degree	342	23.6
Would rather not say	120	8.3
Not asked[b]	567	39.2
Smoking habits		
Never smoker	1090	75.3
Ex-smoker	72	5.0
Social smoker	192	13.3
Regular smoker	94	6.5

[a]where percentages do not total 100% this is due to missing data
[b]This question was not available for University of Sheffield students

fourth component was labelled 'convenience, red meat & alcohol', because it had high factor loadings for red meat and savoury foods requiring little or no preparation, and it was the only component with a positive loading on alcoholic drinks. There were also high factor loadings for fried food, pasta and rice, ready-made sauces, pizza, chips, alcoholic drinks, processed meat, red meat and offal, and eggs; there was a strong negative factor loading for low fat/low calorie yogurts.

Correlational analyses

Pearson's correlation coefficients between dietary pattern scores and energy intake were calculated. These are displayed in Table 3. There was a weak negative correlation between the 'vegetarian' pattern and energy intake ($r = -0.096$; $p < 0.01$), but a weak positive correlation between the 'health-conscious' pattern and energy

Table 2 Factor loadings of the 55 food groups in the four principal components extracted from the PCA of frequency of food intake data of 1448 university students

Food group (% variance)	Vegetarian (8.4%)	Snacking (5.7%)	Health-conscious (4.2%)	Convenience, red meat & alcohol (3.4%)
Pulses, beans & lentils	**0.642**	− 0.113	0.216	
Tofu	**0.627**			0.105
Meat alternatives	**0.586**	0.126	− 0.109	0.121
Hummus	**0.585**		0.147	
Chicken/poultry	*−0.456*		0.106	0.277
Processed meat	*−0.453*	0.277		**0.354**
Red meat & offal	*−0.439*	0.163	0.134	**0.332**
Biscuits, cakes & sweets		**0.623**		− 0.106
Milk & cream-based desserts		**0.531**	0.160	
Confectionery	− 0.174	**0.524**		
Crisps & savoury snacks		**0.413**	−0.170	0.253
White bread	−0.141	**0.393**	−0.209	0.214
Fruit juice		**0.354**		
Other bread	0.104	**0.342**		
Canned fruit	0.101	**0.320**	0.100	−0.124
Fruit squash (not low calorie)		0.293	−0.182	
Other yogurts		0.276	0.216	−0.105
Other spread		0.251		
Added sugar in tea, coffee & cereal		0.239		0.128
Quiche	0.201	0.218		0.124
Fatty fish & canned tuna	−0.120		**0.616**	
White fish & shell fish	−0.157		**0.531**	
Nuts	**0.324**		**0.491**	
Eggs	−0.151	− 0.120	**0.477**	**0.350**
Fresh fruit	0.174		**0.443**	−0.108
Other green vegetables, onions & salad items	**0.369**	−0.258	**0.376**	0.127
Oat- & bran-based breakfast cereals		−0.172	**0.372**	−0.170
Herbal & green tea	0.313	−0.153	**0.365**	
Low fat & low-calorie yogurts			**0.334**	−0.308
Tea & coffee		0.122	0.251	
Fried food				**0.503**
Pasta & rice	0.135			**0.451**
Ready-made sauces				**0.396**
Pizza		**0.327**	−0.171	**0.392**
Chips	− 0.160	0.301	− 0.221	**0.379**
Alcoholic drinks				**0.328**
Butter	−0.166	0.137		0.312
Mayonnaise, salad cream & other dressings	−0.115	0.249	0.225	0.277
Cream		0.128	0.198	0.209
Crispbread	0.144		0.132	−0.179
Peas			0.115	
Boiled, mashed, roast & jacket potatoes	−0.211	0.261		0.113
Root vegetables & sweetcorn	0.237		0.300	

Table 2 Factor loadings of the 55 food groups in the four principal components extracted from the PCA of frequency of food intake data of 1448 university students *(Continued)*

Food group (% variance)	Vegetarian (8.4%)	Snacking (5.7%)	Health-conscious (4.2%)	Convenience, red meat & alcohol (3.4%)
Baked beans		0.112		0.112
Wheat bran			0.124	− 0.136
Low calorie squash & fizzy drinks		0.115		
Non-white bread				
Low fat, olive & pufa spread			−0.124	
Fizzy drinks (not low calorie)	−0.180	**0.332**	− 0.204	0.282
Jam, marmalade & honey		0.255		−0.125
Cheese	0.214	0.145		0.218
Water		−0.253	0.292	
Milk	−0.162	0.107	0.120	0.106
Other breakfast cereals	−0.150	0.168	− 0.194	
Soups	0.209	0.125	0.215	

Food groups with factor loadings ≥0.10 & ≤ − 0.10 are displayed; those ≥0.32 are highlighted in bold and those ≤ − 0.32 are italicised

intake ($r = 0.271$; $P < 0.01$). The 'snacking' and 'convenience, red meat and alcohol' dietary patterns exhibited the strongest correlations with energy intake ($r = 0.582$ and $r = 0.547$ respectively). Owing to these significant associations, energy-adjusted nutrient intakes were used to explore relationships with dietary patterns scores. There were strong positive correlations ($0.5 \geq r < 0.6$; $p < 0.01$) between the 'vegetarian' pattern and energy-adjusted intakes of fibre, copper and thiamin. The 'health-conscious' pattern was the most nutrient dense, with significant, positive, strong correlations ($0.5 \geq r < 0.7$; $p < 0.01$) for energy-adjusted intakes of selenium, vitamin D, vitamin B12, and biotin. The 'snacking' pattern was strongly positively correlated with energy-adjusted non-milk extrinsic sugars (NMES) ($r = 0.524$; $P < 0.01$). Alcohol intake (energy-adjusted) was negatively correlated with scores on the 'snacking' pattern ($r = -0.317$; $P < 0.01$). Only intake of total sugars (energy-adjusted) was strongly and negatively correlated with the 'convenience, red meat & alcohol' pattern ($r = -0.577$; $P < 0.01$).

General linear models

Adjusted mean pattern scores by demographic and cooking/eating behaviour variables from the GLMs are provided in Table 4 (Model 1) and Table 5 (Model 2). The text that follows summarises the key findings.

Pattern 1 – Vegetarian

In Model 1 (demographic variables only) female gender ($p < 0.001$), middle age group ($p = 0.020$), moderate leisure-time activity levels ($p = 0.045$) and ex-smoker status ($p = 0.025$) were independently associated with higher scores on the vegetarian dietary pattern. Attendance at Ulster University was independently associated with lower 'vegetarian' pattern scores ($p < 0.001$).

In Model 2 (demographic variables & food/eating related variables), female gender ($p < 0.001$), middle age group ($p = 0.020$), greatest self-reported cooking ability ($p = 0.036$), least frequent consumption of pre-prepared foods ($p = 0.047$) and lower consumption of animal products ($p = 0.036$) were independently associated with higher 'vegetarian' pattern scores. Attendance at Ulster University ($p < 0.001$) was independently associated with lower scores.

Pattern 2 – Snacking

In Model 1, low leisure-time physical activity ($p < 0.001$), attendance at Ulster University ($p = 0.003$), full time student status ($p = 0.001$) and living with parents/other relatives ($p < 0.001$) were independently associated with higher 'snacking' pattern scores.

In Model 2, lower leisure-time physical activity participation ($p = 0.012$), attendance at Ulster University ($p = 0.029$), living with parents/other relatives or in university catered accommodation ($p = 0.033$), and full-time student status ($p < 0.001$) were independently associated with greater pattern score. Infrequent consumption of meals prepared from raw ingredients ($p < 0.001$), and frequent consumption of pre-prepared foods ($p < 0.001$) and ready meals/take-aways ($p < 0.001$) were also independently associated with high 'snacking' pattern scores.

Pattern 3 – Health-conscious

In Model 1, 'very active' physical activity levels ($p < 0.001$), 'White Other' ethnicity ($p = 0.004$) and third year of undergraduate study ($p = 0.041$) were independently

Table 3 Pearson's correlations between dietary pattern scores and estimated average daily nutrient intakes from frequency of food intake data

	Vegetarian		Snacking		Health-conscious		Convenience, red meat & alcohol	
Nutrient	Absolute	Adjusted	Absolute	Adjusted	Absolute	Adjusted	Absolute	Adjusted
Energy (kcal)	−0.096 [Y]		**0.582** [Y]		0.271 [Y]		**0.547** [Y]	
Protein (g)	−0.304 [Y]	− 0.389 [Y]	0.309 [Y]	− 0.343 [Y]	0.483 [Y]	0.469 [Y]	0.491 [Y]	0.334 [Y]
Total fat (g)	− 0.171 [Y]	− 0.183 [Y]	**0.602** [Y]	0.232 [Y]	0.291 [Y]	0.116 [Y]	**0.535** [Y]	0.134 [Y]
Total carbohydrate (g)	0.073 [Y]	0.322 [Y]	**0.633** [Y]	0.316 [Y]	0.101 [Y]	− 0.287 [Y]	0.330 [Y]	− 0.358 [Y]
NMES (g)	−0.163 [Y]	− 0.110 [Y]	**0.696** [Y]	**0.524** [Y]	− 0.124 [Y]	− 0.393 [Y]	0.234 [Y]	− 0.174 [Y]
Saturated fat (g)	− 0.266 [Y]	− 0.326 [Y]	**0.638** [Y]	0.347 [Y]	0.166 [Y]	− 0.098 [Y]	0.485 [Y]	0.080 [Y]
Monounsaturated fat (g)	− 0.241 [Y]	− 0.306 [Y]	**0.558** [Y]	0.144 [Y]	0.302 [Y]	0.142 [Y]	**0.507** [Y]	0.091 [Y]
Polyunsaturated fat (g)	0.018 [Y]	0.143 [Y]	0.430 [Y]	−0.026	0.336 [Y]	0.209 [Y]	0.492 [Y]	0.137
Total sugars (g)	0.019	0.123 [Y]	**0.602** [Y]	0.333 [Y]	0.295 [Y]	0.154 [Y]	0.043	**−0.577** [Y]
Fibre (g)	0.443 [Y]	**0.551** [Y]	0.080 [Y]	−0.259 [Y]	0.386 [Y]	0.306 [Y]	0.096 [Y]	−0.207 [Y]
Sodium (mg)	0.113 [Y]	0.286 [Y]	0.439 [Y]	−0.002 [Y]	0.313 [Y]	0.172 [Y]	0.436 [Y]	0.040 [Y]
Potassium (mg)	0.035	0.196 [Y]	0.360 [Y]	−0.240 [Y]	0.472 [Y]	0.451 [Y]	0.352 [Y]	−0.212 [Y]
Calcium (mg)	0.073 [Y]	0.183 [Y]	0.449 [Y]	0.106 [Y]	0.315 [Y]	0.189 [Y]	0.199 [Y]	−0.258 [Y]
Magnesium (mg)	0.229 [Y]	0.461 [Y]	0.253 [Y]	−0.347 [Y]	**0.509** [Y]	0.482 [Y]	0.304 [Y]	− 0.197 [Y]
Iron (mg)	0.147 [Y]	0.332 [Y]	0.247 [Y]	−0.350	0.339 [Y]	0.214	0.400 [Y]	− 0.017
Copper (mg)	0.343 [Y]	**0.545** [Y]	0.229 [Y]	−0.256 [Y]	0.458 [Y]	0.387 [Y]	0.340 [Y]	− 0.035
Zinc (mg)	−0.264 [Y]	−0.318 [Y]	0.289 [Y]	− 0.382 [Y]	0.391 [Y]	0.304 [Y]	0.483 [Y]	0.080 [Y]
Selenium (mg)	−0.221 [Y]	− 0.208 [Y]	0.208 [Y]	− 0.259 [Y]	**0.584** [Y]	**0.555** [Y]	0.423 [Y]	0.115 [Y]
Iodine (μg)	− 0.260 [Y]	− 0.247 [Y]	0.259 [Y]	− 0.065	**0.524** [Y]	0.488 [Y]	0.126 [Y]	−0.224 [Y]
Vitamin A (μg)	0.132 [Y]	0.163 [Y]	0.050	− 0.129 [Y]	0.362 [Y]	0.314 [Y]	0.065	− 0.095 [Y]
Vitamin E (mg)	0.163 [Y]	0.286 [Y]	0.347 [Y]	−0.022	**0.505** [Y]	0.447 [Y]	0.244 [Y]	− 0.145 [Y]
Vitamin D (μg)	−0.136 [Y]	− 0.113 [Y]	0.015	− 0.209 [Y]	**0.645** [Y]	**0.613** [Y]	0.159 [Y]	−0.009
Thiamin (mg)	0.484 [Y]	**0.558** [Y]	0.217 [Y]	0.010	0.044	−0.059	0.200 [Y]	0.004
Riboflavin (mg)	−0.223 [Y]	− 0.216 [Y]	0.338 [Y]	− 0.090 [Y]	0.394 [Y]	0.298 [Y]	0.210 [Y]	−0.258 [Y]
Niacin (mg)	−0.359 [Y]	−0.429 [Y]	0.221 [Y]	− 0.377 [Y]	0.465 [Y]	0.408 [Y]	0.408 [Y]	0.008
Vitamin B_6 (mg)	−0.210 [Y]	− 0.226 [Y]	0.266 [Y]	− 0.435 [Y]	0.332 [Y]	0.199 [Y]	0.439 [Y]	− 0.011
Vitamin B_{12} (mg)	− 0.315 [Y]	− 0.311 [Y]	0.180 [Y]	− 0.163 [Y]	**0.583** [Y]	**0.537** [Y]	0.230 [Y]	− 0.065
Folate (μg)	0.177 [Y]	0.313 [Y]	0.191 [Y]	− 0.294 [Y]	0.416 [Y]	0.329 [Y]	0.253 [Y]	− 0.155 [Y]
Biotin (μg)	0.088 [Y]	0.169 [Y]	0.100 [Y]	−0.319 [Y]	**0.690** [Y]	**0.673** [Y]	0.212 [Y]	− 0.123 [Y]
Vitamin C (mg)	0.202 [Y]	0.244 [Y]	0.163 [Y]	−0.017 [Y]	0.299 [Y]	0.237 [Y]	0.009	− 0.197 [Y]
Alcohol (g)	0.023	0.064	−0.020	− 0.317 [Y]	0.026	− 0.086 [Y]	0.345 [Y]	0.180 [Y]

[Y]$P < 0.01$

Correlation coefficients between absolute nutrient intakes and relative nutrient intakes adjusted for energy intakes are both shown. Correlation coefficients ≥0.5 are highlighted in bold

associated with higher scores on the 'health-conscious' pattern. Youngest age group ($p = 0.015$) and attendance at University of Sheffield were independently associated with lower scores ($p < 0.001$).

In Model 2, the five significant demographic factors identified in Model 1 remained independently associated with 'health-conscious' pattern scores. Additionally, reporting being 'able to cook a wide range of meals from raw ingredients' ($p = 0.002$), daily consumption of meals made from raw ingredients ($p < 0.001$) and pre-prepared foods ($p = 0.002$), greatest amount of money spent on food (≥50/week) ($p < 0.001$), at least occasional consumption of animal products ($p < 0.001$) and infrequent skipping of breakfast ($p < 0.001$) were independently associated with higher health-conscious pattern scores. Rare – compared to occasional or almost daily - consumption of take-aways/ready meals was associated with lower scores ($p = 0.042$).

Table 4 General Linear Model 1 – Demographic Variables

	Vegetarian		Snacking		Health-conscious		Convenience, red meat & alcohol	
Lack of fit	*p* = 0.612		*p* = 0.330		*p* = 0.280		*p* = 0.012	
Demographic variable	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value
Gender								
Male	**0.082**	**< 0.001**	−0.315	0.074	0.378	0.132	**0.475**	**< 0.001**
Female	**0.304**		−0.428		0.469		**−0.117**	
Age								
17–21	**0.133**[a]	**0.020**	−0.326	0.424	**0.262**[b]	**0.015**	0.228	0.496
22–25	**0.339**[a]		−0.429		**0.434**[a]		0.210	
26–29	**0.197**		−0.361		**0.574**[b]		0.100	
Leisure-time physical activity								
Not very active	**0.184**[a]	**0.045**	**−0.171**[ab]	**< 0.001**	**0.029**[ab]	**< 0.001**	**0.250**[a]	**0.032**
Moderately active	**0.308**[a]		**−0.356**[ac]		**0.383**[ac]		**0.097**[a]	
Very active	**0.177**		**−0.588**[bc]		**0.857**[bc]		**0.191**	
BMI								
< 18.5	0.292	0.221	−0.281	0.391	0.437	0.055	0.139	0.092
18.5–24.9	0.289		−0.436		0.407		0.073	
25–29.9	0.154		−0.432		0.574		0.144	
≥ 30	0.156		−0.339		0.275		0.361	
Smoking status								
Never	**0.086**[a]	**0.025**	−0.333	0.270	0.404	0.173	**−0.026**[ab]	**< 0.001**
Ex	**0.421**[a]		−0.393		0.387		**0.121**[c]	
Social	**0.159**		−0.254		0.562		**0.311**[ac]	
Regular	**0.225**		−0.507		0.340		**0.310**[b]	
Ethnicity								
White British	0.214	0.441	−0.299	0.810	**0.263**[a]	**0.004**	0.206	0.585
White Irish	0.364		−0.381		**0.276**[b]		0.254	
White Other	0.182		−0.322		**0.545**[ab]		0.140	
Mixed	0.105		−0.352		**0.627**		0.297	
Asian/Asian British	0.281		−0.272		**0.309**		0.211	
Black/Black British	0.003		−0.274		**0.048**		−0.041	
Other	0.103		−0.705		**0.882**		0.489	
Rather not say	0.531		−0.370		**0.437**		−0.123	
Year of study								
1st year UG	0.212	0.194	−0.240	0.154	**0.477**[a]	**0.041**	0.179	0.134
2nd year UG	0.080		−0.439		**0.503**		0.203	
3rd year UG	0.090		−0.475		**0.614**[a]		0.139	
≥ 4th year UG	0.091		−0.431		**0.480**		0.410	
Postgraduate	0.177		−0.374		**0.282**		0.309	
Other	0.687		−0.272		**0.182**		−0.166	
Term-time accommodation								
Uni catered	0.129	0.963	**−0.104**[a]	**< 0.001**	0.176	0.068	0.374	0.053
Uni self-catered	0.245		**−0.517**[b]		0.236		0.219	
Private with friends	0.242		**−0.397**[a]		0.341		0.201	

Table 4 General Linear Model 1 – Demographic Variables *(Continued)*

	Vegetarian		Snacking		Health-conscious		Convenience, red meat & alcohol	
Lack of fit	$p = 0.612$		$p = 0.330$		$p = 0.280$		$p = 0.012$	
Demographic variable	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value
Private on own	0.324		**−0.265**		0.450		−0.275	
Parents/relatives	0.173		**−0.076[bc]**		0.524		0.175	
Partner	0.269		**− 0.306[c]**		0.456		0.187	
Parents/partner + children	0.138		**−0.247**		0.290		0.074	
Children only	0.218		**−0.555**		0.344		0.254	
Other	0.268		**−0.879**		0.992		0.402	
University								
Sheffield	**0.146[abc]**	**< 0.001**	**−0.370[a]**	**0.003**	**0.098[abcd]**	**< 0.001**	0.166	0.270
Ulster	**−0.376[adef]**		**−0.214[ab]**		**0.318[aef]**		0.299	
KCL	**0.398[bd]**		**−0.569[b]**		**0.541[be]**		0.237	
Southampton	**0.227[e]**		**−0.264**		**0.584[cf]**		0.221	
St Andrews	**0.719[cf]**		**−0.442**		**0.576[d]**		−0.027	
Faculty								
Arts	0.334	0.234	−0.308	0.527	0.456	0.766	0.275	0.277
Social science	0.180		−0.357		0.464		0.191	
Engineering	0.123		−0.416		0.400		0.153	
Science	0.216		−0.453		0.357		0.177	
Medicine & health	0.261		−0.324		0.440		0.099	
Full-time vs. part-time student status								
Full-time	0.183	0.582	**−0.109**	**0.001**	0.381	0.560	0.246	0.378
Part-time	0.263		**−0.634**		0.466		0.113	

Independent associations between dietary pattern scores and non-nutrient variables. *p* values < 0.05 are highlighted in bold. Common superscript letters indicate significant post-hoc differences between categories within each variable

Pattern 4 – Convenience, red meat & alcohol

In Model 1, male gender ($p < 0.001$), lowest leisure-time physical activity levels ($p = 0.032$), and regular/social smoking status ($p < 0.001$) were independently associated with higher scores on the 'convenience, red meat & alcohol' diet pattern. An independent inverse association between living alone in private accommodation and score on this pattern approached significance ($p = 0.053$).

In Model 2, higher pattern scores were independently associated with male gender ($p < 0.001$), regular/social smoking status ($p < 0.001$), most frequent consumption pre-prepared foods ($p = 0.040$), frequent consumption of ready-meals/take-aways ($p < 0.001$), frequent breakfast skipping ($p < 0.001$), regular consumption of animal products ($p < 0.001$) and greater amounts of money spent on food ($p < 0.001$). Lower scores were independently associated with living alone ($p = 0.026$) and spending less money on food ($p < 0.001$).

Discussion

This study aimed to identify dietary patterns within a UK university student population and to delineate the socio-demographic, lifestyle and other behavioural characteristics of students favouring these patterns. Dietary patterns analysis unveiled heterogeneity in food choice with students following four major dietary patterns: 'vegetarian', 'snacking', 'health-conscious' and 'convenience, red meat & alcohol'. These patterns explained approximately one fifth of the variance in food intake. Students' gender, age, geographical location and cooking ability were associated with differences in pattern behaviour. Clustering of lifestyle risk factors with dietary patterns was also evident, with less healthful dietary patterns associated with smoking, low physical activity and take-away consumption. Students tending to the 'convenience, red meat & alcohol' pattern reported spending more money on food each week.

The 'vegetarian', 'snacking' and 'health-conscious' patterns identified here are analogous to those previously reported

Table 5 General Linear Model 2 – Demographic + Eating related variables

	Vegetarian		Snacking		Health-conscious		Convenience, red meat & alcohol	
Lack of fit	$p = 0.001$		$p = 0.748$		$p = 0.426$		$p = 0.017$	
Demographic variable (n)	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value
Gender								
Male	**1.119**	**< 0.001**	*Not entered into model*		*Not entered into model*	*N/A*	**0.645**	**< 0.001**
Female	**1.304**						**0.129**	
Age								
17–21	**1.140[a]**	**0.020**	*Not entered into model*	*N/A*	**−0.047**	**0.049**	*Not entered into model*	*N/A*
22–25	**1.301[a]**				**0.113[a]**			
26–29	**1.314**				**0.161[b]**			
Leisure-time physical activity								
Not very active	1.258	0.183	**0.270[ab]**	**0.012**	**−0.187[ab]**	**< 0.001**	0.436	0.117
Moderately active	1.297		**0.208[ac]**		**0.064[ac]**		0.327	
Very active	1.199		**0.034[bc]**		**0.350[bc]**		0.399	
BMI								
< 18.5	*Not entered into model*	*N/A*	*Not entered into model*	*N/A*	0.110	0.215	*Not entered into model*	*N/A*
18.5–24.9					0.057			
25–29.9					0.173			
≥ 30					−0.037			
Smoking status								
Never	1.190	0.292	*Not entered into model*	*N/A*	*Not entered into model*	*N/A*	**0.224[ab]**	**< 0.001**
Ex	1.321						**0.272[c]**	
Social	1.264						**0.520[ac]**	
Regular	1.230						**0.532[b]**	
Ethnicity								
White British	*Not entered into model*	*N/A*	*Not entered into model*	*N/A*	**−0.107[ab]**	**0.016**	*Not entered into model*	*N/A*
White Irish					**−0.080[c]**			
White Other					**0.123[ac]**			
Mixed					**0.243**			
Asian/Asian British					**0.033**			
Black/Black British					**− 0.081**			
Other					**0.370[b]**			
Rather not say					**0.106**			
Year of study								
1st year UG	*Not entered into model*	*N/A*	*Not entered into model*	*N/A*	**0.048[a]**	**0.004**	*Not entered into model*	*N/A*
2nd year UG					**0.069**			
3rd year UG					**0.200[a]**			
≥ 4th year UG					**−0.008**			
Postgraduate					**− 0.158**			
Other					**0.304**			
Term-time accommodation								
Uni catered	*Not entered into model*	*N/A*	**0.427[ab]**	**0.033**	*Not entered into model*	*N/A*	**0.595**	**0.026**
Uni self-catered			**0.159[ac]**				**0.495**	
Private with friends			**0.149[bd]**				**0.469**	

Table 5 General Linear Model 2 – Demographic + Eating related variables *(Continued)*

	Vegetarian		Snacking		Health-conscious		Convenience, red meat & alcohol	
Lack of fit	*p* = 0.001		*p* = 0.748		*p* = 0.426		*p* = 0.017	
Demographic variable (n)	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value
Private on own			**0.218**				**0.030[a]**	
Parents/relatives			**0.390[cde]**				**0.431[a]**	
Partner			**0.248[e]**				**0.378**	
Parents/partner + children			**0.378**				**0.293**	
Children only			**– 0.178**				**0.430**	
Other			**−0.256**				**0.364**	
University								
Sheffield	**1.218[abc]**	**< 0.001**	**0.136[a]**	**0.029**	**−0.270[abcd]**	**< 0.001**	*Not entered into model*	*N/A*
Ulster	**0.894[adef]**		**0.242[abc]**		**0.069[aef]**			
KCL	**1.424[bd]**		**0.036[b]**		**0.196[be]**			
Southampton	**1.298[eg]**		**0.337**		**0.187[cf]**			
St Andrews	**1.424[cfg]**		**0.103[c]**		**0.197[d]**			
Full-time vs. part-time student status								
Full-time	*Not entered into model*	*N/A*	**0.442**	**< 0.001**	*Not entered into model*	*N/A*	*Not entered into model*	*N/A*
Part-time			**−0.101**					
Cooking/eating-related variables								
Cooking ability								
Wide range	**1.350[ab]**	**0.036**	0.024	0.190	**0.257[ab]**	**0.002**	0.261	0.297
Limited range	**1.239[ac]**		0.015		**0.065[ac]**		0.301	
Pre-prepared only	**1.125[bc]**		0.151		**−0.101[bc]**		0.527	
Unable to cook at all	**1.292**		0.492		**0.082**		0.459	
Animal food consumption								
Regular meat-eater	**−0.171[abcd]**	**< 0.001**	0.187	0.080	**0.445[a]**	**< 0.001**	**0.500[ab]**	**< 0.001**
Flexitarian	**0.291[aefg]**		0.199		**0.488[b]**		**0.185[ac]**	
Lacto-ovo	**1.635[beh]**		0.314		**0.101**		**0.534[c]**	
Ovo	**1.707[chi]**		0.319		**−0.459[ab]**		**0.201[b]**	
Vegan	**2.795[dghi]**		−0.238		**−0.196**		**0.517**	
Meals made from scratch								
Every day	1.322	0.136	**−0.060[abc]**	**0.001**	**0.339[abc]**	**< 0.001**	**0.622**	**< 0.001**
Most days	1.272		**0.146[ade]**		**0.198[ade]**		**0.495**	
Occasionally	1.172		**0.246[bd]**		**−0.034[bd]**		**0.345**	
Rarely/never	1.240		**0.350[ce]**		**−0.200[ce]**		**0.088**	
Meals made from pre-prepared foods								
Every day	**1.302[a]**	**0.047**	**0.338[a]**	**< 0.001**	**0.178[ab]**	**0.002**	**0.591[abc]**	**0.040**
Most days	**1.151[bc]**		**0.304[bc]**		**0.046[acd]**		**0.336[a]**	
Occasionally	**1.231[bd]**		**0.143[bd]**		**−0.069[bce]**		**0.265[b]**	
Rarely/never	**1.321[acd]**		**−0.102[acd]**		**0.148[de]**		**0.356[c]**	
Ready-meals/take-aways								
Every day	1.511	0.257	**0.584[ab]**	**< 0.001**	**0.273**	**0.042**	**0.552[a]**	**< 0.001**
Most days	1.222		**0.290[cd]**		**0.025[a]**		**0.570[bc]**	
Occasionally	1.130		**−0.036[bd]**		**−0.068[b]**		**0.302[cd]**	

Table 5 General Linear Model 2 – Demographic + Eating related variables *(Continued)*

	Vegetarian		Snacking		Health-conscious		Convenience, red meat & alcohol	
Lack of fit	$p = 0.001$		$p = 0.748$		$p = 0.426$		$p = 0.017$	
Demographic variable (n)	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value	Adjusted mean pattern score	*p* value
Rarely/never	1.143		**−0.155**[acd]		**0.073**[ab]		**0.125**[abd]	
Meals in university cafeteria								
Every day	1.156	0.062	0.153	0.547	0.141	0.922	0.375	0.336
Most days	1.253		0.245		0.047		0.485	
Occasionally	1.311		0.170		0.069		0.372	
Rarely/never	1.286		0.115		0.046		0.317	
Skipped breakfast								
Every day	1.358	0.062	0.221	0.101	**−0.179**[ab]	**< 0.001**	**0.514**[ab]	**< 0.001**
Most days	1.276		0.257		**0.066**[c]		**0.609**[cd]	
Occasionally	1.193		0.114		**0.126**[ad]		**0.307**[ace]	
Rarely/never	1.179		0.091		**0.290**[bcd]		**0.119**[bde]	
Skipped lunch/dinner								
Every day	1.245	0.991	0.089	0.131	0.284	0.404	**0.001**	**0.012**
Most days	1.252		0.236		0.066		**0.443**	
Occasionally	1.261		0.116		−0.031		**0.503**	
Rarely/never	1.248		0.241		−0.016		**0.602**	
Amount spent on food								
< £20	1.278	0.268	0.101	0.534	**−0.171**[abcd]	**< 0.001**	**0.162**[abcd]	**< 0.001**
£20–29	1.269		0.146		**−0.005**[aef]		**0.344**[aef]	
£30–39	1.251		0.150		**0.138**[beg]		**0.385**[b]	
£40–49	1.333		0.264		**0.096**[eh]		**0.481**[ce]	
≥ £50	1.127		0.192		**0.320**[dfgh]		**0.564**[df]	

Independent associations between dietary pattern scores and non-nutrient variables. *p* values < 0.05 are highlighted in bold. Common superscript letters indicate significant post-hoc differences between categories within each variable

in adult and adolescent UK populations [22, 23]. The 'convenience, red meat & alcohol' pattern shares features (positive factor loadings for red meat, chips, alcohol) with a major dietary pattern (labelled drinker/social) reported among approximately 480 20–25 year olds in Northern Ireland, derived from 7-day diet history data [24].

The 'snacking' and 'convenience, red meat and alcohol' patterns have common features with published data on the food preferences of British university students [2, 4]. Existing studies allude to non-prudent consumption patterns, reporting low consumption of fruit and vegetables alongside high intakes of confectionery, alcohol, and fried, ready-made and convenience foods [2–4].

We have shown that both the 'snacking' and 'convenience, red meat and alcohol' patterns were least nutrient-dense. Indeed it is noteworthy that these two patterns were additionally positively correlated with energy intake and did not feature fruit and vegetables; dependence on such a pattern may increase risk of positive energy balance and hence weight gain. The 'health-conscious' pattern, which had a favourable nutrient profile - being particularly dense in micronutrients such as biotin, vitamin B12, vitamin D and selenium - is at odds with the stereotype of student eating patterns, but concurs with published research on dietary patterns among UK adults [21, 22] and a small-scale study of university students in Birmingham, UK [4].

It is of note that a vegetarian diet was the predominant pattern identified in the current study, and indeed 10% of students described themselves as vegetarian. The latter figure is less than that reported in a survey of over 3000 university students studying in Northern Ireland, which reported that 22% of students did not eat meat [3]. Although a vegetarian pattern has been described in the wider UK diet pattern literature [21–23], it was a minor component, in keeping with the low prevalence of vegetarianism among British adults nationally (3%) [25].

Whilst high rates of binge drinking have previously been documented among student populations [3, 26], and there is a popular stereotype of students as heavy drinkers, only one pattern ('convenience, red meat &

alcohol') was high in alcoholic beverages. Furthermore students following this pattern were also more likely to smoke, have frequent consumption of take-aways and pre-prepared foods and engage in lower levels of physical activity. This clustering of behaviours is important, since the negative health outcomes associated with multiple lifestyle risk factors are greater than the sum of individual health risk behaviours [27]. Conversely students favouring more healthful dietary patterns reported greater engagement in other health-promoting lifestyle choices, including not smoking, greater participation in physical activity. Aggregation of lifestyle behaviours has previously been reported in both university student and adult populations [26–28].

Gendered food preferences were also evident, especially in relation to meat consumption. Specifically, female students favoured a 'vegetarian' diet, whilst male students scored highly on the 'convenience, red meat & alcohol' pattern. Greater meat and fast food consumption among male students has previously been reported, and vegetarianism is more prevalent amongst female students [3, 24]. Although a recent British student study observed no gender differences between eating patterns [4], this study lacked detailed dietary assessment.

Dietary preferences also varied between participating universities. Generally, students at Ulster University favoured less healthful patterns, whilst those at the Universities of Southampton, St Andrews and KCL tended towards more healthful diets. Students attending the University of Sheffield were least likely to adopt a 'health-conscious' dietary pattern. This gradient is congruent with national data, which indicates that the population of Northern Ireland consumes a diet of poorer quality than the UK as a whole [29]. Dietary gradients were also evident in relation to geography in a comparative study of university students from seven universities across the UK, although absence of information on specific university location limits comparison [2].

It is also possible that dietary differences observed between universities may arise because of socioeconomic gradients across universities. Missing data on social class for students at the University of Sheffield precluded adjustment for this possibility. However information from the Higher Education Statistics Agency (HESA) indicates an SES gradient between universities: a greater proportion of students at Ulster University are from manual occupational backgrounds than from KCL, Sheffield and Southampton (no data available for St Andrews) [30]. Maternal education data for Ulster, KCL, St Andrews & Southampton corroborated these differences (data for University of Sheffield not available). The wider literature consistently reports a positive association between socioeconomic status and diet quality across UK population groups [21, 23, 28]. However, the tendency for students at the University of Sheffield to score lowest on a 'health-conscious' diet is not in line with this explanation.

The possibility of selection bias should be considered. There were differences in recruitment method between the University of Sheffield and Ulster University (recruitment email distributed directly to all students via a global mailing list), and the other three participating sites (e.g. study advertisement on student volunteers webpage). These recruitment differences may have biased the sample towards health-motivated students at KCL, St Andrews and Southampton.

The lack of association between university attended and consumption of the 'convenience, red meat & alcohol' diet also deserves attention. This homogeneity suggests that this pattern is pervasive across all universities studied, substantiating popular beliefs that the diet of UK university students is one of poor quality.

This study also revealed that older students favoured more healthful dietary patterns and there was evidence of a positive linear relationship between age and scores on the 'health-conscious' pattern. It is possible that as students mature they become increasingly aware of the impact of dietary choices on health and well-being, and health thus becomes an increasingly important determinant of food choice. Studies among the general UK adult population report similar age effects [21, 22]. A student survey conducted in Northern Ireland reported a positive gradient in diet quality by year of study [3]. In contrast, other student-specific research has failed to detect an association between eating habits and age (or year of study), although most of these studies have not collected detailed dietary data [2, 4, 10, 26].

Finally, 45% of the current sample reported limited (or non-existent) cooking ability, being at best only able to cook a limited range of meals from raw ingredients. Students with poor cooking ability were less likely to adopt healthier (vegetarian; health-conscious) diets than their more skilled counterparts. This association has not been documented among a university student population, but corroborates associations found in several adult studies [31, 32]. No association, however, was identified between cooking ability and scores on the less healthful dietary patterns (snacking; convenience, red meat & alcohol). Whilst it is likely that students who lack culinary skills may be forced to rely on convenience foods to ensure meal provision, other factors such as time pressures and (lack of) cooking enjoyment may be more salient in determining students' decisions around consumption of these foods [33, 34] .

Study strengths and limitations

The current study had a number of strengths and limitations that should be acknowledged. FFQs are not optimal for the measurement of absolute dietary intake, but the use of a dietary pattern approach permitted ranking according to food group intake and so was considered appropriate. Furthermore, use of an FFQ allowed dietary intake to be captured over a 3-month semester and facilitated recruitment of a large, geographically diverse sample, albeit a convenience one. Ideally, the sampling frame would have included a greater number of universities and involved stratification by year of study, subject group and socioeconomic indices in order to give a nationally representative profile of student eating patterns. Moreover, only health-sciences students were recruited at Southampton, which may represent a source of bias.

The small number of students recruited from St Andrews may been seen as an under-representation of students from a Scottish university, but it should be noted that the total student population at St Andrews (population of around 8000 students) is much smaller than that of Sheffield, Ulster and KCL (between 25,000 and 30,000 students). It should also be noted that all dietary studies suffer from selection bias, in which more health- or diet-aware individuals choose to participate. Consequently, the prominence of the vegetarian and health-conscious dietary patterns may have been over-estimated in this study. Indeed, the BMI distributions were also biased towards healthy, in keeping with other student surveys [4, 26].

There was lack of fit in statistical models for 'convenience, red meat and alcohol', and 'vegetarian' dietary patterns. It should be noted that these models are developmental and clearly only cover some of the potential antecedents of following such patterns. Convenience, red meat, alcohol and vegetarian dietary choices are likely to be influenced by a raft of social, cultural and political factors, which have not been included in the model. For example, it is recognised that adoption of a vegetarian diet is related to concern about the environment and animal welfare, as well as for health reasons and weight management [35, 36]. Similarly, there is enormous heterogeneity in motives for drinking alcohol including coping, enhancement of social status, religious practice, personality type and alcohol availability [37, 38].

Implications for policy and future research directions

Importantly, policy makers must recognise not all students consume poor diets at university: a large group of students consumed nutritionally favourable and health-promoting diets and do not appear in need of dietary intervention. However, students who consumed poor diets and practised unfavourable lifestyle behaviours were also identified, which may have long-term health effects. Targeted interventions towards these students are necessary. Furthermore, contemporary policy to limit red meat and alcohol consumption has greatest relevance to male students. University policy to improve students' diets should also incorporate efforts to promote student engagement in cooking and food preparation, and increased availability of low cost healthier food items.

This study also highlights a number of future research needs. Replication of this research among a large representative sample of UK university students would be pertinent. Secondly, in light of the association between cooking ability and dietary consumption patterns, investigation of the potential for a cooking skills intervention to improve dietary intake is warranted. Finally, the public health impact of dietary patterns and other lifestyle risk factors established during university become most important if these behaviours track forward into working adult life and represent a blueprint for long-term dietary preferences. Longitudinal research is now needed to investigate this possibility.

Conclusion

This study provides a unique insight into the dietary patterns of UK university students along with associated nutritional content. It has identified a number of antecedents of both healthful and unhealthful dietary practices. Four patterns emerged, with evidence of more healthful dietary practices amongst female and older students, and those with greater self-reported cooking ability. Students in Northern Ireland appeared to favour less healthful dietary patterns than those in Great Britain. Male students tended towards a diet founded on convenience food, red meat and alcohol; this pattern was germane to all participating universities. These findings are relevant to future health promotion interventions and behaviour change in this important population.

Additional file

Additional file 1: Table S1. Details of the constituent foods comprising the 55 foods/food groups entered into the PCA. **Table S2.** Eating behaviours and other eating-related characteristics of the Phase 1 sample. (DOCX 26 kb)

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions
This manuscript represents original work, which has not been published previously and is not being considered by another Journal. The authors' responsibilities were as follows: EFS, JMR & MEB conceived and designed the study. EFS was primarily responsible for data collection and analysis, with advice from JMR. EFS wrote the first draft of the manuscript, with help from MEB. JC & LKP facilitated recruitment of students from the University of St Andrews and Ulster University, respectively. All authors contributed to revisions and approval of the final manuscript.

Ethics approval and consent to participate
Ethical approval was obtained from 3 participating university. University of Sheffield Medical School Research Ethics Review, SMBRER288; University of St Andrews Teaching and Research Ethics Committee, MD11298; University of Ulster Research Ethics, 14/0096. University of Sheffield ethical approval covered the research at Kings College London and Southampton.
Each participant gave informed consent on the first page of the web-survey. The provision of consent enabled access to the full survey.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interest.

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