

BMJ Open Adherence to Mediterranean diet in Italy (ARIANNA) cross-sectional survey: study protocol

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ABSTRACT

Introduction There is evidence, although limited, that the Italian population has been no longer following a Mediterranean dietary pattern. The ARIANNA (Adherence to the Mediterranean Diet in Italy) project consists of a survey-based cross-sectional study with the objective of gaining a greater knowledge of adherence to the Mediterranean Diet and its main determinants in different age groups of the Italian population.

Methods/analysis The ARIANNA study will involve males and females aged ≥7 years, born and resident in Italy, and proficient in Italian. The voluntary enrolment will be in the period between March 2023 and May 2023. The data, which will include sociodemographic factors and dietary habits, will be collected through a web-based questionnaire. Adherence to the Mediterranean Diet will be assessed through the use of two validated score systems: the Mediterranean Diet Quality Index in children and adolescents for participants aged ≤16 years and the Mediterranean Diet Serving Score for participants aged ≥17 years. A review of the scientific literature will be carried out to collect historical data on adherence to the Mediterranean dietary pattern in the Italian population, which will be compared with those collected within this project.

Ethics and dissemination The ARIANNA study has been approved by the Ethics Committee of Istituto Superiore di Sanità. The results will be disseminated through peer-reviewed papers, leaflets and documents for the general public. A report will be presented to the national policy makers, to give them the tools to implement appropriate intervention to improve, in necessary, the adherence to Mediterranean dietary pattern in Italy.

BACKGROUND

The Mediterranean diet (MD) is a dietary pattern characterised by a high intake of vegetables, fruits and nuts, cereals (especially whole-grain cereals), legumes and olive oil; a moderate-to-high intake of fish; a low-to-moderate intake of dairy products; a low intake of saturated fats, meat and poultry; and a moderate intake of wine.^{1,2} In the late 1950s, the American physiologist Ancel Keys noticed that the eating behaviours of the population

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A nationwide study to investigate the adherence to Mediterranean diet in Italy and association with main sociodemographic factors and adherence to special diets.
- ⇒ The first study specifically designed to provide the Italian policy makers the results to implement evidence-based interventions.
- ⇒ Rapidity, simplicity, affordability of web-based collection of data.
- ⇒ Participants' membership will be voluntary and their involvement should be boosted through media and press-campaign.
- ⇒ Bias due to the online self-administered questionnaire.

living in the areas bordering the Mediterranean Sea, in particular, Crete and Cilento in Southern Italy, were associated with reduced rates of cardiovascular diseases and higher longevity. The term MD was coined in 1960 by Keys and his wife Margaret in their book 'How to Eat Well and Stay Well the Mediterranean Way'.^{3,4}

The MD is a part of a model based on cultural, historical, social, territorial and environmental heritage and it is based on lifestyles including conviviality, sharing of meals, moderation, tradition and connection to the territory. Over the years, a great deal of significant epidemiological evidence has accumulated on the effects of this dietary pattern on health outcomes. It is now well established that the MD pattern is associated with a lower prevalence of obesity and a reduced risk of cardiovascular events, cancer, type 2 diabetes, metabolic syndrome and overall mortality.⁵ It also represents a sustainable food model characterised by a lower environmental impact because of the higher intake of plant-based foods, that contribute least to energy and water consumption, agriculture land use, and emissions of greenhouse gases.⁶



Recent reports in the scientific literature have shown a shift away from the traditional dietary pattern, such as MD, in Mediterranean populations including young and adult Italian population.⁷⁻⁹ Indeed, in a systematic literature review by Obeid *et al*, it was pointed out a low to moderate adherence to MD in the past 10 years in the Mediterranean countries.¹⁰ Especially among adolescents, dietary habits have changed considerably due to globalisation and westernisation. Two recent studies available on the young Italian population reported respectively that only 5% of primary school children and 16% of high school students have good adherence to MD.^{11 12} In fact, several surveys of the Italian population have shown a gap in adherence to MD between young and adult individuals and a higher adherence in adults.¹³⁻¹⁵ On the other hand, other recent studies have found no association between MD adherence and age,⁷ and no difference in MD adherence according to the age.¹⁰ Thus, the exact magnitude of MD drop-out is not known and, above all, it is unclear which age groups show this phenomenon most strongly on a national scale.

Aim of the study: Adherence to the Mediterranean Diet in Italy (ARIANNA) project is a survey-based cross-sectional study that aims to evaluate the adherence to the MD and its main determinants in different age groups of the Italian population, using score systems validated and described in scientific literature.

METHODS AND ANALYSIS

Study design and participants

A precision-based approach was employed to calculate the sample size, considering the estimated proportion of subjects compliant with Mediterranean dietary patterns. Since literature reports a wide range of levels of compliance,^{7 16} the required sample size was calculated for an estimated proportion of compliant subjects ranging from 40% to 5%, with a precision of 0.05 at a 0.95 confidence level (1-alpha). Table 1 shows a combination of each expected proportion and related sample size. Computations were performed using the R V.3.4.2 (R Foundation for Statistical Computing, Vienna, Austria).

Table 1 Sample size for different levels of compliance with Mediterranean dietary patterns considering a precision of 0.05 and a 0.95 CI

Proportion of subjects compliant with Mediterranean dietary patterns	N
0.40	1472
0.35	1396
0.30	1289
0.25	1152
0.20	984
0.10	563
0.05	318

Participants in the ARIANNA study will be males and females aged ≥ 7 years, born and resident in Italy, proficient in Italian, and willing to complete the questionnaire on their own initiative. The involvement will be in the period between March 2023 and May 2023, and it will be boosted through traditional and social media, and press-campaign. The geographical distribution of the participants will be assessed by dividing the Italian territory into four macroareas, already identified in previous nutritional studies (North-West, North-East, Centre, South and Islands). Once the data have been obtained, the demographic characteristics of the participants in each area will be checked against those of the others to verify homogeneity. The questionnaires will be administered through an on-line site (<https://www.iss.it/il-progetto-ariana>) and, once the data collection is completed, these will be systematised and processed.

Questionnaire

The questionnaires in the ARIANNA project are web-based, self-administered, anonymous and free. They are divided into two different parts. The first part consists of questions on demographic factors, socioeconomic status, health status and lifestyle. The response formats are closed and structured for: gender (female, male), age (17–20 years, 21–40 years, 41–60 years, 61–80 years, 81 years or more), qualification (none, primary school certificate, lower secondary school certificate, high school diploma, degree, postgraduate study), adherence to special diets (none, coeliac disease, food allergy, lactose intolerance, veganism, vegetarianism, religious reasons), main concomitant pathology (none, type 2 diabetes, hypertension, myocardial infarction, stroke, chronic obstructive pulmonary disease, cancer), occupation (none, employment, coordinated and continuous collaboration, occasional work, self-employment, unemployment). The occupation item is completed with two more questions on the type of contract: fixed-term or permanent, full time or part time. Annual income is an optional questionnaire item and it is provided as: <€5000, €5000–€15 000, €15 000–€30 000, €30 000–€50 000, €50 000–€100 000, >€100 000. Geographical areas of birth and residence are requested as province (second-level administrative division of Italy) and zip code. The number of members within the household (>18 years, 13–18 years and ≤ 12 years) and frequency of physical activity (hour/week) are also requested. The second one includes questions on participants' dietary habits, different according to the age and to the score system selected to evaluate MD adherence.

Adherence to the MD

The evaluation of MD adherence, both in adults and youth, is possible through the use of specific scoring systems, which are useful tools for identifying dietary patterns of a given population.^{17 18} A systematic review of the literature was carried out to decide on the score systems to be used in this study to assess adherence to the

Table 2 KIDMED (Mediterranean Diet Quality Index in children and adolescents) items²⁰

	Scoring
Takes a fruit or fruit juice every day	+1
Has a second fruit every day	+1
Has fresh or cooked vegetables regularly once a day	+1
Has fresh or cooked vegetables more than once a day	+1
Consumes fish regularly (at least 2–3/week)	+1
Goes >1/week to a fast food restaurant (hamburger)	-1
Likes pulses and eats them >1/week	+1
Consumes pasta or rice almost every day (five or more per week)	+1
Has cereals or grains (bread, etc) for breakfast	+1
Consumes nuts regularly (at least 2–3/week)	+1
Uses olive oil at home	+1
Skips breakfast	-1
Has a dairy product for breakfast (yoghurt, milk, etc)	+1
Has commercially baked goods or pastries for breakfast	-1
Takes two yoghurts and/or some cheese (40 g) daily	+1
Takes sweets and candy several times every day	-1
KIDMED Index: poor ≤3, medium 4–7, high ≥8	

MD. The aim was to find a simple, quick and valid tool that would best suit the online collection of data. Based on the results obtained, two different a priori score systems were chosen: the KIDMED (Mediterranean Diet Quality Index in children and adolescents) for participants aged ≤16 years, and the MDSS (Mediterranean Diet Serving Score) for participants aged ≥17 years. The KIDMED test was chosen because it is an easy tool, as well as being one of the most widely used survey tools for the youth. On the other hand, MDSS was chosen for its rapidity, simplicity, accuracy, for being based on the frequency of consumption of foods and food groups, and not having to collect information on nutrients and quantities in grams of foods.

The KIDMED questionnaire could be self-administered or conducted by trained interviewers (paediatrician, dietitian, etc) and it consists of 16 questions. There are 4 questions denoting a negative connotation to the MD and 12 questions denoting a positive connotation. It is only possible to answer ‘yes’ or ‘no’, and in case of an affirmative answer, questions denoting negative connotation are scored with -1, while positive connotation questions are scored with +1.^{19 20} The final score, obtained by the sum of the values, is the index of adherence to the MD, also called KIDMED score (range 0–12 points), and it is ranged into three levels of diet: (1) >8, high, (2) 4–7, medium and (3) <3, poor^{20 21} (see table 2). In the

Table 3 Mediterranean Diet Serving Score items²²

	Recommendation*	Score
Fruit	1–2 servings/main meal†	3
Vegetables	≥2 servings/main meal†	3
Cereals‡	1–2 servings/main meal†	3
Potatoes	≤3 servings/week	1
Olive oil§	1 serving/main meal†	3
Nuts	1–2 servings/day	2
Dairy products¶	2 servings/day	2
Legumes	≥2 servings/week	1
Eggs	2–4 servings/week	1
Fish	≥2 servings/week	1
White meat**	2 servings/week	1
Red meat††	<2 servings/week	1
Sweets‡‡	≤2 servings/week	1
Fermented beverages§§	1–2 glass/day	1
Total score		24

*According to the Mediterranean Diet Pyramid.²⁴
 †Main meals: breakfast, lunch and dinner.
 ‡Bread, breakfast cereals, rice and pasta.
 §Olive oil used on salads or bread or for frying
 ¶Milk, yoghurt, cheese, ice cream.
 **Poultry.
 ††Pork, beef or lamb.
 ‡‡Sugar, candies, pastries, sweetened fruit juices and soft drinks.
 §§Wine and beer.

ARIANNA study, respondents aged ≤16 years are asked to complete the KIDMED questionnaire together with a parent or a guardian.

The MDSS consists of 14 items and the MDSS total score ranges between 0 and 24 points for adults/elderly, and between 0 and 23 for adolescents. Individuals whose intake is within the number of recommended servings are awarded a score of 3, 2, or 1 point for recommendations expressed in times/meal, times/day or times/week, respectively. In adults, 1 point is added for alcohol intake equivalent to 1 and 2 glasses of fermented drinks for females and males, respectively. A score of 0 is given when the number of servings/meal, week or day is higher or lower than the recommendation²² (see table 3). In the ARIANNA questionnaire frequency of intake of the 14 food groups is asked participants as usual number of times of consumption per day (fruit, vegetables, cereals, olive oil, dairy products) and per week (dried fruit and nuts, potatoes, legumes, eggs, fish, white meat, red meat, sweets, wine or beer). The final score will be computed by the sum of each item score and the range between 0 and 24 points will be considered for all respondents aged ≥17 years. Furthermore, the obtained MDSS total scores will be divided into tertiles, to classify respondents into MD adherence groups (low, medium and high).



Statistical analysis

Data obtained will be managed by the Istituto Superiore di Sanità.

Initially, the homogeneity of the data by geographical area will be verified and their representativeness at national level will be checked through a comparison with the Italian National Institute of Statistics database.²³ A descriptive analysis of the data will then be carried out, using mean and SD or median and IQR and absolute frequencies and percentages (%). Parametric or non-parametric tests, depending on variable distributions, will be applied to evaluate the associations among all variables.

A multivariate regression analysis will be used to assess the potential factors influencing adherence to the MD. Some of the possible factors that will be studied include: age, gender, geographical area of birth and residence, qualification, income, occupation, concomitant pathology, adherence to special diet. A $p < 0.05$ (two tailed) will be considered statistically significant. Statistical analysis will be performed using the statistical software StataSE V.17 for Windows (StataCorp).

Patient and public involvement

No patient was involved in the development and design of the research, and subjects will be not involved in the recruitment and conduction of the study. Once the participants to the study complete the questionnaire, the obtained score will be shown.

If the adherence to the MD results to be poor or medium, some suggestions to increase it will be provided on screen to the participants, inviting them to consult useful information and some traditional recipes on the website. Respondents with high MD adherence, on the other hand, will be invited to continue following healthy eating habits and to consult traditional recipes to vary their dietary pattern, as well.

Ethics and dissemination

The ARIANNA study has been approved by Ethics Committee of the Istituto Superiore di Sanità (approval n AOO 0028080 on 27 July 2021). The consent to participate, and to collect and process personal data, is given electronically (ticking the corresponding box) on the project website, before accessing the questionnaire, in accordance with the European Commission General Data Protection Regulation (679/2016). As instructed by the Data Protection Officer of the Istituto Superiore di Sanità, consent to participate for individuals under 16 years old is given electronically by a parent or a guardian, who is asked to complete the questionnaire together with the minor. Participants will be anonymised, because no identity-related information (first name, last name, date of birth) is asked in the questionnaire.

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role in the design of the study, collection, analysis and interpretation of the data.

The results will be disseminated to scientists and epidemiologists through scientific peer-reviewed papers, to the general public through leaflets and articles on not-specialised journals and magazine. A report will be presented to the national policy makers, to give them the tools to implement appropriate intervention to improve, in necessary, the adherence to Mediterranean dietary pattern in Italy.

Contributors MS and DG conceived the protocol and designed of the work; EC and RDB designed the questionnaire, DG, GL and FI performed the statistical analysis, FZ, SG and MG designed the on-line software used in the work; EC and MS have drafted the work. All the Authors approved the present version of the paper.

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