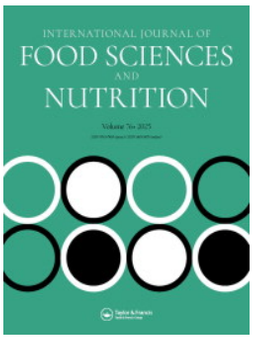

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The Southern Italian Children, Adolescents and paRents cOhort Study on nutrition and health: protocol of the ICARO Study

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ABSTRACT

In Italy, around 30% of children and adolescents are overweight or obese, with higher rates in the South. Parental dietary habits influence children's eating behaviours, yet most studies focus on food composition without considering the level of food processing. The Nova classification categorises foods by processing levels, suggesting that food processing may affect health beyond nutritional content. Ultra-processed foods (UPFs), such as sugary drinks and packaged snacks, are calorie-dense and contain cosmetic food additives. High UPF consumption is linked to obesity, chronic diseases, and poor cognitive development in children. However, no comprehensive up-to-date assessment of UPF consumption among Italian children exists. To address this gap, the ICARO Study was launched in Southern Italy as a web-based cohort of children, adolescents, and their parents. This study aims to evaluate UPF consumption and its correlates, and assess the impact of a nutrition education intervention on reducing UPF intake at the family level.

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Ultra-processed foods; Mediterranean Diet; population study

Introduction

Childhood obesity is a major public health concern worldwide, as overweight or obese children are likely to become overweight or obese adults, with serious health and social consequences, including a higher risk of premature death and disability in adulthood (Fernández-Alvira et al. 2013; Ahrens et al. 2014; Jilani et al. 2018; Hernández-Quevedo et al. 2019).

In Italy, an estimated 30% of children are overweight or obese, with a clear north-to-south gradient reflected by a higher prevalence of kids being overweight or obese in southern Italian areas (Istituto Superiore di Sanità 2023). Parents play a powerful role in children's eating behaviour, by creating food environments and structuring their children's first experiences with food and eating through their own beliefs, food practices, perspectives, eating attitudes, knowledge, and understanding of the benefits of food and nutrients on health (Savage et al. 2007; Romanos-Nanclares et al. 2018).

Actually, several studies reported a great influence of parental dietary habits on dietary behaviours of their children regardless of demographic characteristics such as sex, age, socioeconomic status and country (Mahmood et al. 2021). Evidence suggests that encouraging children to consume a variety of foods is associated with healthier eating behaviours (e.g. higher intake of fruits and vegetables), while using unhealthy foods as rewards could increase the child's preferences for these food items (Lo et al. 2015). Parental modelling also seems to directly influence children's diet (De Bourdeaudhuij et al. 2008; Davison et al. 2017).

Of notice, most of these prior studies analysed parents and children's diet almost exclusively by evaluating food composition (i.e. calorie, macro- and micronutrient contents), with no or little attention paid to degree of food processing. However, such a nutrient-centred approach has some important limitations, since other aspects in the diet-health-disease relationship are increasingly acknowledged as important as nutrients in shaping health risk at population level (Fardet and Rock 2022).

The Nova classification (Monteiro 2009) was proposed as a different way to categorise foods based on the extent and purpose of processing rather than

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considering their nutritional composition, postulating that processing may be as relevant to health as food composition, possibly through mechanisms that are triggered by non-nutritional components of these foods, such as degradation and artificialisation of the food matrix, cosmetic additives, food contact materials, or neo-formed compounds (Monteiro 2009; Fardet and Rock 2022). The term ultra-processed food (UPF) indicates industrially manufactured ready-to-eat or ready-to-heat formulations made mostly or entirely from substances extracted from foods or derived from food constituents often containing added flavours, colours, emulsifiers and other cosmetic additives (Monteiro 2009). Most importantly, these industrial formulations are designed to maximise palatability and consumption through a combination of calorie-dense ingredients and chemical additives (Lemos et al. 2022). Examples of typical UPFs are carbonated drinks, processed meat, fruit yogurt, sweet or savoury packaged snacks, ice-cream, chocolate, candies (confectionery), mass-produced packaged breads and buns, and many others (Monteiro 2009). UPFs now constitute a large part of the world's food consumption and is dramatically high in non-Mediterranean countries, representing almost 60% of total calories in the USA (Baraldi et al. 2018) and in the UK (Rauber et al. 2018), 42% in Australia (MacHado et al. 2019) and 46% in Canada (Polsky et al. 2020), with substantial differences between adults and children/adolescents. In Mediterranean countries such as Spain and Italy, the proportion of food that is ultra-processed among adults is about 24% and 17%, respectively (Blanco-Rojo et al. 2019; Ruggiero et al. 2021), possibly because home cooking is still part of a traditional Mediterranean diet.

In the United Kingdom, 65% of calories eaten by primary and secondary school children are from UPF (Martines et al. 2019) and a similarly high intake of UPF (>55%) is seen in paediatric populations of the United States and Canada (Moubarac et al. 2017; Neri et al. 2019).

Data from the INHES Study established in 2010-2013 indicated that the average energy intake from UPFs was 26% in a sample of 506 Italian children/adolescents aged 5–19 years (Ruggiero et al. 2021). In the I.Family study including a large population of children, adolescents and adults recruited from eight European countries from 2013 to 2018, the mean contribution of UPFs to the total energy intake was 46% both in Italian children and adolescents (Lauria et al. 2021).

Robust and well-conducted cohort studies worldwide found that a large dietary share of UPF is associated with shorter survival (Pagliai et al. 2021; Bonaccio et al. 2022) and an increased risk of non-communicable diseases, including cardiovascular disease (CVD), type 2 diabetes and some cancers (Lane et al. 2024). Amongst children, high consumption of UPFs has been linked to adiposity and cardiometabolic risk factors (Khoury et al. 2024), as well as behavioural and cognitive issues (Liu et al. 2023).

Besides being typically nutrient-poor (i.e. low content of fibre, vitamins and other nutrients, while being rich in calories, unhealthy fats and salt) (Martini et al. 2021), UPFs may trigger additional mechanisms unrelated to their nutritional composition, that may underpin the link between heavy UPF intake and non-communicable chronic diseases. As first, any type of processing fundamentally alters food matrix, typically in a detrimental manner (Matos et al. 2021). Moreover, the cosmetic food additives found in highly processed products also have uncertain effects on health, as well as the packaging of UPF which is a major source of chemicals (e.g. bisphenols and phthalates) that have the potential to act as xenohormones (Fenichel et al. 2013), which may disrupt hormonally mediated processes critical for growth and development during gestation, infancy, or childhood (Liu et al. 2023).

Given the rising popularity of UPFs globally, also in Mediterranean countries, the issue of food processing should be prioritised in relevant dietary recommendations with emphasis on consumption of minimally/unprocessed foods. The Southern Italian Children, Adolescents and PaRents COhort Study on Nutrition and Health (ICARO Study) has been proposed to a) evaluate dietary intakes according to the degree of food processing of children, adolescents and their parents living in Southern Italy; b) analyse major correlates associated with dietary intakes and eating habits; and c) evaluate the effect of a nutrition education intervention on UPF intake in children, adolescents and adults.

Results from the ICARO Study may provide new evidence to inform the development of targeted intervention strategies at both the population and family levels, aimed at reducing the consumption of UPFs and promoting unprocessed or minimally processed diets within families.

Experimental design and study population

The ICARO Study is designed as a web-based prospective cohort of children, adolescents and their parents/caregivers residing in Southern Italy; recruitment will start in the southern Italian region of Molise, and will be later extended to the Campania and Sicily

regions, and possibly involve other Southern Italian regions willing to participate.

The ICARO study consists of two parts, namely Study 1 (observational) and Study 2 (intervention Study).

The main objectives of the ICARO Study (Study 1) are to:

1. Evaluate the diet of participants (i.e. children, adolescents and their parents/caregivers) in terms of food composition (i.e. calorie, macro- and micronutrient contents) and complemented by a timely and innovative approach based on the evaluation of food processing, in line with the notion that the nutrient balance of a food is only a small part of its overall health potential (Fardet and Rock 2022);
2. Investigate major demographic, socioeconomic, behavioural, psychosocial, and other environmental factors as potential correlates of diet and diet-related habits of both children, adolescents and parents;
3. Analyse parental influence (e.g. food attitudes and nutrition knowledge) on children and adolescents diet quality and eating habits.

Within the ICARO Study population, an Intervention Study (Study 2) is planned to increase nutrition awareness, and promote adherence to a minimally-processed Mediterranean Diet and reduce the dietary share of UPFs at family level.

Study 1 – establishment of a web-based prospective cohort of children, adolescents and their parents/caregivers residing in Southern Italy

Eligible participants to the ICARO Study are parents/caregivers of 2–13 years old children, and adolescents aged 14-18 years at recruitment residing in Southern Italy.

Exclusion criteria include not being fluent in Italian language, refusal to sign informed consent and lack of an electronic device with internet access (i.e. computer, mobile phone). To calculate the sample size, the data published by The Italian National Institute of Statistics (ISTAT) on the 1st of January, 2022 were taken as reference, where it reflected that the Italian population in South Italy is composed of 13,512,083 inhabitants. The required sample size for the population survey (Study 1) has been estimated at 1,500 individuals.

This calculation is based on a 95% confidence level and a margin of error of ±2.53%, ensuring sufficient precision to capture the true population parameters. Participants' data will be collected through on-line questionnaires available on the Study's website (https://studioicaro.neuromed.it/) and collected at baseline and updated yearly (i.e. dietary intake, anthropometric data, health status, socio-demographics, lifestyle, physical activity, behavioural, psychosocial and other environmental factors). Participants will be recruited through multimedia campaigns (e.g. regional newspapers, posters, internet, social networks), contacts with schools also through the regional school system, professional channels (e.g. paediatricians, general practitioners, pharmacists), and targeted meetings with the general population that will call for volunteers by providing details on the study's specific web-site where volunteers can subscribe.

Once the registration form is completed and the consent form signed (mandatory steps), the participant will receive a confirmatory e-mail providing a username and password to access the questionnaires included in the study. The sampling will be distributed across four seasons (excluding Christmas, Easter and mid-August periods). One parent/caregiver for each family will be asked to fill the questionnaires for their children aged <14 years; adolescents can directly complete the questionnaires although may be assisted by parents/caregivers or teachers. The questionnaire will however clearly ask participants to indicate who assisted in fulfilling the study questionnaires.

Ethical issues

The study is conducted according to the guidelines laid down in the Declaration of Helsinki on the ethical principles for medical research in human beings, and has been granted the approval of the Ethics Committee of the IRCCS Neuromed, Pozzilli (IS), Italy. Electronic informed consent will be obtained from all participants (both parents/caregivers will be asked to sign the informed consent also for their children aged <18 y) before the initiation of the study. The study has been registered at clinicaltrials.gov. (NCT05784376).

Materials

Assessment of dietary intake and eating habits in children and adolescents

Parents/caregiver are asked to complete a 3-day food record (FR) for each child aged <14 years. Written instructions are given to parents for the correct use of FR and how to quantify food portions; they are also instructed to let the children follow their usual diet. Parents are asked to provide a detailed description of each food and drink consumed by the child, including the method of preparation, recipes and place of

consumption, whenever possible. A team of trained nutritionists is responsible for reviewing and coding the FRs. Dietary data are analysed through the Metadieta MyDiet software application (METEDA S.r.l., Roma, Italy), which is linked to the Italian database of food composition (Salvini et al. 1998). Adherence to the Mediterranean Diet will be assessed through the KIDMED index (Serra-Majem et al. 2004), a 16-item Mediterranean Diet Quality Index based on principles sustaining Mediterranean dietary patterns as well as those that undermine it. Eating habits are evaluated through three different questions on: a) breakfast consumption; b) food frequency and c) family meals using questionnaires developed and validated in the Health Behaviour in School-Aged Children (HBSC) Study (Currie et al. 2014).

Development and validation of novel questionnaires

The ICARO Study has developed and will validate two novel questionnaires. The Nova-FFQ KIDS is a food frequency questionnaire (FFQ) designed to assess dietary intakes based on the Nova classification in children and adolescents aged 2-18 years. Currently, there are no FFQs tailored to the Nova classification for the Italian population of children and adolescents. The Nova-FFQ KIDS is a semi-quantitative FFQ developed by adapting previously validated adult instruments (Dinu et al. 2021), with additional information on specific food groups commonly consumed by children and adolescents. The Icaro-FKQ (I-FKQ) has been designed to assess knowledge of the Mediterranean diet in the Italian population in children, adolescents, and adults.

Assessment of dietary intake and eating habits in parents/caregivers

The validated 94-item Nova FFQ (NFFQ) (Dinu et al. 2021) is used to estimate the usual intake (g/day) of the four Nova food groups of parents/caregivers. Food items are grouped under 9 section headings: (a) fruit and nuts, (b) vegetables and legumes, (c) cereals and tubers, (d) meat and fish, (e) milk, dairy products, and eggs, (f) oils, fats, and seasonings, (g) sweets and sweeteners, (h) beverages, (i) other, and (g) an additional table to note frequently consumed items not present in the previous sections. The level of food processing of all foodstuffs, beverages, and ingredients was classified according to the processing classification system based on the Nova classification (Monteiro 2009), and reflecting increasing levels of industrial food processing: 1) fresh or minimally processed foods (e.g. fruits and vegetables, meat and fish); 2) processed culinary ingredients (e.g. honey, butter); 3) processed foods with salt, sugar, or oil (e.g. canned or bottled vegetables and legumes, canned fish); 4) ultra-processed foodstuffs described as industrial formulations with five or more ingredients, which are often packaged, branded, highly palatable, and convenient, and are consumed as snacks or to replace homemade dishes. They may include additives, sweeteners, and added micronutrients to fortify them. The contribution of UPF to the diet is calculated as the proportion (%) of UPF in the total weight of food and beverages consumed by creating a weight ratio, or as energy ratio.

In adults, adherence to the Mediterranean Diet is determined through the 14-item Mediterranean Diet Adherence Screener (MEDAS) consisting of 12 questions on food consumption frequency and 2 questions on food intake habits considered characteristic of a traditional Mediterranean diet (Schröder et al. 2011).

Assessment of key variables in children/adolescents

Amongst children, the ICARO study collects the following data: a) parent-reported demographic factors and family affluence (Currie et al. 2014); b) parent-reported weight and height; c) parent-reported physical activity through the HBSC questionnaires measuring both the leisure-time vigorous physical activity (VPA) and the moderate-to-vigorous physical activity (MVPA) (Currie et al. 2014); parent-reported sedentary behaviour through a set of questions aimed at evaluating time spent in three primary components of youth sedentary behaviours (playing computer/videogames; using a computer for activities other than games, and watching television) (Currie et al. 2014). The same questionnaires are administered to adolescents who will be asked to self-report this information. Also, an assessment of health and well-Being will be assessed through questions on Self-Rated Health, Life satisfaction, the HBSC Symptom Checklist, and Body Image (Currie et al. 2014).

Assessment of key variables in parents/caregivers

Socioeconomic and demographic data are obtained through semi-structured questionnaires, including information on, e.g. age, educational level, household income, occupation, cohabitation with a spouse or partner, place of residence. Anthropometric measurements (i.e. weight and height) are self-reported, as are parents' nutrition knowledge and attitudes to food (Schröder et al. 2011). Information on breastfeeding and complementary feeding, and caesarean delivery are also collected. The Child Feeding Questionnaire is administered to evaluate parental attitudes to child weight and parental feeding practices (Buratta et al. 2021).

Optional questionnaires

Parents/caregivers and adolescent participants are given the opportunity to complete a set of the additional questionnaires on a voluntary basis to address other key potential correlates of diet and eating habits at family level. For adolescents, some examples include: smoking and alcohol use; school environment (e.g. school engagement, school pressure, student support, teacher support); peer support; Electronic Media Communication (EMC) (Currie et al. 2014).

For parents/care givers, optional questionnaires include the following: Child Eating Behaviour Questionnaire (CEBQ) assessing eating style in children (Wardle et al. 2001); Pittsburgh Sleep Quality Index (PSQI) assessing sleep quality and disturbances (Curcio et al. 2013); International Physical Activity Questionnaire - Short Form to evaluate levels of physical activity (Craig et al. 2003); Morningness-Eveningness Questionnaire to determine morningness-eveningness in human circadian rhythms (Horne and Ostberg 1976); Brief Resilience Scale to evaluate psychological resilience (Smith et al. 2008); 8-Item Duke/UNC Functional Social Support Questionnaire (DUFSSQ) assessing the strength of the person's social support network (Broadhead et al. 1988); Perceived Stress Scale (PSS-4) to assess stress levels (Cohen et al. 1983); Patients' Health Questionnaire (PHQ-9) to evaluate depressive symptoms (Kroenke et al. 2001); General Anxiety Disorder (GAD-7) to evaluate general anxiety symptoms (Spitzer et al. 2006).

Statistical analysis. The contribution of UPFs to the diet will be calculated as the proportion (%) of UPF in the total weight of food and beverages consumed by creating a weight ratio, or as an energy ratio. Qualitative variables will be represented by frequency and percentage, quantitative variables expressed by mean ± standard deviation, median and inter quartile range. Differences in UPF intake across potential correlates will be assessed by multivariable general linear (or logistic) regression analysis, taking into account the clustering of data in families.

Study 2 –intervention study to increase awareness on UPFs and promote adherence to a minimally-processed Mediterranean diet and reduce the dietary share of UPFs

Study 2 is designed as a two-arm, parallel-group, randomised controlled trial (RCT) to assess the impact of a nutrition education intervention targeting parents and adolescents living in Southern Italy, and delivered *via* text messages through mobile applications (e.g. WhatsApp, e-mails). The primary outcomes will be changes in dietary intakes and nutrition knowledge, while the secondary outcome will be changes in mental health (e.g. stress, anxiety, and well-being) in both parents and children. The intervention will be delivered over a 20-week period and will consist of two brief videos per week.

The content of the educational videos varies between the intervention and control groups. Participants in the intervention group receive content specifically focused on UPF consumption, including how to identify UPFs using the Nova classification. These videos also promote adherence to a Mediterranean-style diet through behavioural tips and visual examples. Participants in the control group receive an equivalent number of videos focused on general education, such as hydration, meditation, mental health and quality of sleep, but without any specific reference to diet nor UPFs.

All videos are approximately 1–2 min in length, age-appropriate, and designed to be accessible to both parents and adolescents, using simple language and visual to maximise engagement and comprehension.

Inclusion Criteria:

- Families with at least one child aged 2–18 years
- Scholars aged ≥14 years
- Parents and scholars willing to participate in nutrition education sessions.
- Ability to complete baseline and follow-up assessments (on-line)

Exclusion Criteria:

- Participants with diagnosed food allergies or medical conditions that require specific dietary management.
- Evidence of severe/chronic diseases, including metabolic or cardiovascular disease, or disease that may influence metabolism (e.g. cancer, diabetes, thyroid disease);
- Taking any prescription medication or other drug that may influence metabolism (e.g. diet/weight-loss medication, asthma medication, blood pressure medication, psychiatric medications, corticosteroids, or other medications at the discretion of the PI and/or study team);
- Pregnancy, lactation;
- Eating disorders or psychological conditions, such as (but not limited to) clinical depression, bi-polar disorders, that would be incompatible with safe and successful participation in this study, as determined by investigators;

- Volunteers with strict dietary concerns (e.g. vegetarian or kosher diet, food allergies);
- Volunteers unwilling or unable to give informed consent;
- Severe cognitive impairment (documented presence of Alzheimer's or Parkinson diseases);
- Body mass index >40 kg/m^2;
- Difficulties or major inconvenience to change dietary habits;

Participants will be randomly assigned to one of two arms:

1. Intervention Group: Parents and/or scholars will receive the nutrition education program.
2. Control Group: Parents and/or scholars will receive a general health education program unrelated to nutrition, for the same duration, frequency, and format.

The nutrition education intervention will be a comprehensive, behaviourally-based program designed to improve dietary habits, enhance nutrition knowledge, and promote healthy eating patterns in both parents and scholars.

Primary outcomes will be (changes in):

- Consumption of UPFs;
- Adherence to the Mediterranean Diet;
- Nutrition knowledge.

Secondary outcomes (changes in)

- Psychological well-being.

Changes in primary and secondary outcomes will be assessed by self-administered questionnaires through the ICARO Study's website (https://studioicaro.neuromed.it/).

Statistical analysis (Study 2)

Sample size estimation was conducted to detect a meaningful change in primary outcomes (e.g. consumption of UPFs, adherence to the Mediterranean Diet) with a standardised effect size of 0.55, 90% power, and a significance level of $\alpha = 0.01$ to account for multiple outcomes. Based on these parameters, a total of 200 participants (100 per arm) will be required.

The sample size was calculated under the assumption of an intention-to-treat analysis, ensuring that all randomised participants will be included in the primary analyses regardless of their adherence to the intervention.

Changes in continuous outcomes (e.g. dietary intakes, nutrition knowledge scores) from baseline to post-intervention will be assessed within each group using paired t-tests or repeated-measures ANOVA, depending on the data structure. Between-group differences will be tested using independent t-tests or ANCOVA, adjusting for baseline values and potential confounders (e.g. age, socioeconomic status, baseline adherence to the Mediterranean Diet). For categorical outcomes, chi-square tests or logistic regression models will be employed.

Secondary outcomes (e.g. psychological well-being) will be analysed using similar methods, with additional adjustments for baseline mental health scores. Multiple imputation techniques will be applied to handle missing data, and sensitivity analyses will be performed to ensure the robustness of the findings.

At the end of the study, participants will be asked targeted questions to evaluate their compliance with the intervention, participation rates, overall satisfaction, and perceived usefulness of the program. Statistical analyses will be conducted using SAS software.

Discussion

The ICARO project emerged with the aim of investigating Mediterranean diet adherence, the consumption of UPFs, including its potential determinants, and gathering data on nutritional knowledge. The study population involves young participants and their parents residing in southern Italy and the intervention program consists of providing videos with scientific messages.

In the last decades, with the so-called process of the "Nutritional transition" a rapid shift in dietary habits has been reported (Popkin 2003). This phenomenon is often related to the term "Westernization" of the diet and it is associated with the worldwide rise in consumption of UPFs and lower adherence to the Mediterranean diet, especially throughout the developing years (Grosso and Galvano 2016; Baker et al. 2020; Marino et al. 2021). The onset of this mechanism has stimulated extensive research efforts, particularly in light of its association with adverse health effects (Astrup et al. 2008). As a consequence, the impact of Mediterranean diet adherence and UPFs consumption on the health of children and adolescents has been largely studied. Recent research suggested an inverse association between high Mediterranean diet adherence and asthma, allergies and pro-inflammatory biomarkers in children and adolescents (Masini et al. 2024) while the consumption of UPFs was associated with detrimental health effects, especially in the phases of growth and development (i.e. cardiovascular and periodontal diseases, greater levels of

inflammatory biomarkers and higher odds of being overweight and obese) (Mescoloto et al. 2024).

Due to their significant impact on health, there has been an increasing interest in recent years in developing strategies that enable individuals to enhance their knowledge and awareness regarding decision-making and choices that improve their health (Silva et al. 2023). In this sense, technology may provide a rapid, simple, and cost-effective approach to increasing population awareness of the nutritional value and quality of the food they consume. Children, adolescents and young adults are most influenced by digital communication channels in promoting behavioural change (Ludwig et al. 2018; de Sousa et al. 2022). Previous systematic reviews focused on the potential impact of messages (Loescher et al. 2018) mobile apps (Baumann et al. 2022), videos and social media channels (Rose et al. 2017; Kulandaivelu et al. 2023) to induce dietary behaviour change among children and adolescents. Furthermore, children and adolescents exhibit heightened sensitivity to their social environments, particularly peers and parents (Harrist and Bakshi 2022). Different studies have examined the impact of parental presence on the food and non-food choices of their children, emphasising the crucial role of caregiver involvement in intervention programs (Xu et al. 2015; Yee et al. 2017; Mahmood et al. 2021).

It is expected that the findings of the ICARO project may confirm current scientific results and include improvements in the nutritional knowledge of participants. The present strategy, if successful, may offer a method to implement a cost-effective health promotion program in children, adolescents and their caregivers, and encourage participants awareness and behavioural change to increase adherence to the Mediterranean diet while decreasing the intake of UPFs. Although currently focused on Southern Italy, the ICARO Study offers valuable insights into at-risk populations. We acknowledge that cultural and dietary differences may limit generalisability; however, the methodology is designed to be adaptable and may be extended to other Italian regions in future phases. The potential barriers of the study may be the use of self-reported questionnaires to collect participants' data and limited feedback on video viewing engagement.

Conclusions

In conclusion, as consumption of UPFs continues to dominate the food supply in high-income countries worldwide, understanding the key factors that drive or correlate with this trend has become increasingly important. The findings from this study will provide valuable insights into the patterns of UPF consumption and its primary determinants among Southern Italian families. This research is crucial for identifying the underlying influence on dietary choices, and may inform the development of targeted public health strategies aimed at reducing UPF intake. Ultimately, these strategies could help mitigate the potential long-term health risks associated with excessive consumption of such highly processed foods, contributing to better dietary habits and improved health outcomes in the population.

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Authors contributions

MB, ER, GG, ADC, and LI conceived and designed the ICARO study. ER, GDC, MDR, AF, FL, and NP acquired and managed the data. MB, ER, ADC, GG, and NP drafted the manuscript. GdG, ADC, GG and LI critically revised this manuscript.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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