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Study Protocol

Iranian Trend of Household Dietary Inflammatory Index from 1991 to 2020: Analyzing for Policies - Study Protocol

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ABSTRACT

Background and Objectives: Systemic inflammation has gained increasing attention in the literature due to its critical role in health and the rising prevalence of its risk factors, such as unhealthy diets in middle- and low-income countries. This study aims to calculate the trend of the modified empirical dietary inflammatory index (EDII) for the Iranian population over the past three decades and analyze for policies related to this index.

Materials and Methods: This study analyzes the DII trend using household food expenditure data in Iran. The data on household food purchases were extracted from the annual Household Income and Expenditure Survey conducted by the Iranian Statistics Center between 1991 and 2020. To estimate food intake, adjustments will be made for unpurchased, wasted, lost, and cooked food using specific coefficients.

The DII calculation involves determining the average daily food expenditure for 15 predefined food groups categorized into two main categories: anti-inflammatory and pro-inflammatory foods. The EDII score is calculated by multiplying the amounts of each food group by its respective scores and weights. Additionally, the EDII will be adapted to Iranian dietary patterns, as investigated in Esmaillzadeh's study.

For the qualitative phase, a one-page graphic questionnaire will be designed to raise awareness among policymakers about the issue. Stakeholder analysis will be conducted using Brugha's stakeholder analysis method. Policy documents, articles, and relevant texts will be reviewed to identify key concepts and themes. To determine policy components, the Walt and Gilson health policy framework and Shiffman and Smith policy making frameworks will be applied.

Keywords: Dietary Inflammatory Index (DII), Prospective study, Dietary policies

Introduction

Non-communicable diseases (NCDs) are among the growing and costly challenges worldwide (1, 2). They are also one of the top priority issues in Iran's health system (3). When we talk about NCDs, we refer to four chronic diseases that lead to the highest mortality rates globally, caused by four major risk factors: alcohol use, tobacco use, unhealthy dietary habits, and low physical activity (4).

Diet is one of the main risk factors for NCDs. Global reports have shown that the three major dietary risk factors are high salt intake (3 million deaths and 70 million years of life lost), low intake of whole grains (3 million deaths and 82 million years of life lost), and insufficient consumption of fresh fruits (2 million deaths and 65 million years of life lost) (5). In Iran, the primary dietary risk factors are low intake of whole grains and high salt consumption (6).

One of the key mechanisms that contributes to the progression of diabetes, cancer, asthma, and cardiovascular diseases (CVD) is chronic inflammation (7). This inflammation is caused by the long-term elevation of inflammatory biomarkers, such as C-reactive protein (CRP), tumor necrosis factor-α (TNF-α), and interleukin-6 (IL-6), in tissues. Literature from the past two decades has

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demonstrated that nutrients such as zinc and vitamin C, or specific dietary patterns with certain restrictions, such as the DASH (Dietary Approaches to Stop Hypertension) or Mediterranean diet (rich in olive oil and vegetables), significantly impact inflammatory biomarkers (8).

The Dietary Inflammatory Index (DII) is a validated indicator that describes the association of major dietary components, such as foods or nutrients, with serum inflammatory biomarkers (9, 10). Food-based EDII is a practical tool for assessing dietary habits in communities and making recommendations. Additionally, the DII can serve as a valuable predictor for policy actions aimed at reducing diet-related mortality at the national level (10).

Diet-related policies are designed to halve NCD mortality. These actions are outlined in frameworks such as the Environmental Policy Index (EPI) (11) and the Nourishing Framework (12). These policy actions are categorized into three main domains: food environment interventions, nutrition education, and improvements to the food chain or food system structure. A study on diet-related policies in Iran, aimed at reducing NCDs using the 4Ps marketing framework, revealed that experts in Iran identified "educational sessions on the principles of healthy eating" in the school curriculum as the most important action (13).

This research is designed with the hypothesis that the EDII trend in the Iranian population has worsened. Additionally, this research is an analytical study on DII-related policies over the past three decades, aimed at prescribing policy implications to reduce the DII score.

Study aims and conceptual frameworks

A mixed-methods approach has been adopted to develop NCD dietary policies due to the complexity of the phenomenon. The overall aim of this study is to present a 30-year trend at the national and subnational levels in Iran. It also aims to analyze diet-related policies based on variations in household DII score trends.

To achieve the overall aim, the study is divided into five phases:

1. **Calculation of EDII scores** and plotting household MEDII trends over the past three decades at the national and subnational levels.
2. **Review of national documents** in Iran to identify dietary policies at the national level.
3. **Analysis of how dietary policies** in Iran have influenced household EDII trends over the past three decades.
4. **Identification of policy actions** to reduce the dietary inflammatory index.
5. **Recommendation of high-priority policy implications** for inclusion in Iran's national agenda.

After obtaining the findings from steps one and two, dietary policies will be evaluated using the Walt Framework (14). The Walt Framework includes four components:

- **Content**: Plans, strategies, goals, and projects.
- **Context**: The environment in which policymaking occurs, including political, economic, social, and cultural conditions.
- **Process**: How decisions are made and policies are implemented.
- **Actors**: People and organizations that influence and are influenced by policies.

The power and position of stakeholders will be analyzed using the Brugha method (15). This method creates a matrix of characteristics, interests, power, position, and influence of stakeholders on policies, making it a suitable and straightforward strategy for stakeholder management.

The **Nourishing Framework** is a coherent and structured action plan aimed at reducing non-communicable diseases through dietary measures. This framework consists of two components:

1. A global search for policy measures promoting healthy diets.
2. A systematic search of databases (laws, government websites, and ministries) of European countries (27 countries).

As part of the World Health Organization's global action plan (16), this framework provides policy options tailored to national, local, and regional contexts based on the target population.

To achieve the fifth aim, the Shiffman framework will be applied to set the policy agenda for identifying relevant policies (17). This framework includes four main components that help explain why some health sector issues and ideas are prioritized at the international or national level while others are not. These four components are:

1. **The power of actors** involved in the initiative.
2. **The power of the idea** used to address the problem.
3. **The nature of the political context** in which the actions are carried out.
4. **The characteristics of the problem** itself.

Study Setting

This study investigates the household EDII in 31 provinces of Iran over the past three decades. Iran, located in West Asia and affiliated with the Eastern Mediterranean Region of the World Health Organization (WHO), spans an area of approximately 1.64 million square kilometers and has an estimated population of 85.92 million in 2024. Over the years, due to changes in political divisions, the number of provinces in Iran has increased. By 2010, there were 31 provinces, compared to 28 in earlier years. Consequently,

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expenditure data have been adjusted to align with the most recent administrative divisions.

In the second part of the study, policies at the national level will be analyzed, including the review of relevant documents and stakeholder analysis.

Details of the study method

Assessment of food intake

This cross-sectional study uses annual household food expenditure data collected in Iran by the Iranian Statistics Center (ISC). Household-purchased food items were extracted from the annual survey of household income and expenditure conducted by the ISC from 1991 to 2020 (18). The Appelhans BM study demonstrated that household purchase data is an accurate estimate of diet quality based on a 24-hour recall, though it may not be valid for specific micronutrients (e.g., vitamin C, potassium, and unsaturated fatty acids) (19). It has also been shown that household expenditure data correlates with food intake by approximately 70% (20).

The **Household Expenditure and Income Survey** has been conducted since 1963 for rural households and since 1968 for urban areas in Iran. The questionnaire was revised in 1991. This dataset collects information annually from May 1 to April 30 in four sections:

1. Household demographic characteristics.
2. Household housing facility information.
3. Household expenditures.
4. Household incomes.

The data include the cost and quantity of food purchased for all common food items consumed by Iranians. Additionally, food items received as gifts or food aid in the last month are also included.

To calculate daily household food intake, the amount of purchased food will be divided by 30. Since the data reflect purchased, not consumed, quantities, adjustments will be made for food waste based on type (e.g., 12% for fruits and vegetables). For certain food items, such as live lamb or poultry, further adjustments will be made for inedible parts. The loss and waste coefficients provided by the Food and Agriculture Organization (FAO) for different regions of the world (21) are applied to ensure realistic data. Cooking coefficients are then used to account for weight changes during preparation. Finally, to calculate the per capita DII, the total food consumption of the household will be divided by the household size.

Dorosty Food Processor (DFP) software will be used to obtain food composition data (22). Finally, the weight and energy of each food item will be entered into SPSS software version 20 for further analysis.

DII calculation method

The Dietary Inflammatory Index (DII) evaluates the inflammatory potential of a diet. It includes negative scores, which indicate an anti-inflammatory diet, and positive scores, which reflect a pro-inflammatory diet (9, 10).

To calculate the EDII:

1. The average daily intake of 15 predetermined food groups is determined. These include:
   - **Anti-inflammatory food groups** (7): fruit juices, fish, yellow vegetables, green leafy vegetables, pizza, tea, and coffee.
   - **Pro-inflammatory food groups** (8): processed meats, red meat, organ meat, other vegetables, refined grains, snacks, high-energy beverages, and tomato.
2. The EDII score is calculated by multiplying the amounts of each food group by the regression weights provided in Tabung's study (10).
3. The overall dietary inflammatory score of each individual is calculated by summing the scores of all food groups.
4. For subnational analysis, the average DII score for individuals in each province is computed.

Due to cultural dietary differences, such as the consumption of margarita pizza and unsweetened juice in Western countries, the EDII designed by Tabung (10) is modified for Iran. Adjustments are made based on proven relationships between fruit juice, pizza, and inflammatory biomarkers in the Iranian diet.

Qualitative study

Identification and Selection of Relevant Documents

Relevant keywords will be searched on the official websites of the Ministry of Agriculture (www.maj.ir), the Ministry of Industry and Trade (www.mimt.gov.ir), the Ministry of Health (www.behdasht.gov.ir), and the Council Researches website (www.rc.majlis.ir) in Iran. Documents, articles, and related texts will be extracted. Manual searches will also be conducted.

Steps for Document Analysis:

1. Identification of main concepts and themes in the subject matter.
2. Review and agreement on themes by two experts.
3. Division of themes into smaller subthemes.

Keywords for Searching Local Websites

Nutrition, food, labeling, standards, taxation, subsidies, advertising, reformulation, financial incentives, regulations, education, counseling, awareness, skills, information, supply chain, food preferences, food choice, food environment, food access, price, income, fruit, vegetables, nuts, red meat, dairy products, legumes, fish, vegetable oils, whole grains, refined grains, sugar, salt, trans fatty acids, policy, and strategy.

Inclusion Criteria

1. The document must reference Iran as the location.
2. The full text must be available.
3. The document must be original.

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Exclusion Criteria:

1. Documents published by non-governmental organizations, the food industry, or campaigns.
2. Speeches, announcements, or summaries.
3. Documents lacking interventions or policy actions.

To ensure authenticity, only documents issued by parliament, the government, or the Supreme Council of Health and Food Security are considered valid (23). Documents must be unbiased, free from conflicts of interest, and relevant to the research objectives. Public documents, such as speeches, reports, and newspaper articles, will also be searched to identify contextual events related to interventions.

The study protocol was reviewed and approved by the Medical School Ethics Committee of Tehran University of Medical Sciences, by the Declaration of Helsinki. All participants will be required to complete an informed consent form prior to their inclusion in the study. The objectives of the study and a summary of the research procedures will be clearly explained to all participants.

Delphi Approach

To collect deeper insights on the research topic, a semi-structured interview will be conducted using a **three-round Delphi method**:

1. **First Round:** Participants will be invited and asked descriptive questions to generate ideas. Ample time will be given for participants to think deeply.
2. **Second Round:** Stakeholders will rate key criteria for NCD policies based on the answers from the first round.
3. **Third Round:** Policies will be rated, and final feedback will be collected to prioritize policies.

According to Miller's theory, a maximum of 9 and a minimum of 5 criteria are acceptable for decision-making (24).

Statistical Analysis

To evaluate differences between quintiles in continuous variables, an ANOVA test will be conducted, while for categorical variables, a chi-square test will be used. Analyses will be performed using SPSS software (version 20; SPSS Inc.). Trends will be analyzed for demographic subgroups, including age groups, sex, education level, household head occupation, and household size. A significance level of 0.05 will be considered, and the P-value test will be two-sided.

Content analysis

To identify the interventions, policy objectives, policy processes, content, and context of the policies, an inductive thematic content analysis approach will be applied to key documents. Questions will be designed by the research team. In the results reporting stage, a comparative analysis using the basic theory (inductive/deductive) method will be conducted (25). For identifying policy interventions, interviews will be analyzed using the framework analysis method (26). Themes will be formed based on Walt's policy triangle and the NOURISHING policy intervention framework. MAXQDA 12.0 software will be used to organize and analyze data.

Identified policies will be classified into three groups:

- **Red:** Interventions not mentioned in Iran's policy documents.
- **Yellow:** Interventions mentioned in Iran's policy documents but not implemented, and are idealistic.
- **Green:** Interventions currently implemented in Iran with an action plan (27).

Stakeholder Analysis

The purpose of this step is to gather information and formulate a plan for stakeholder management to implement the policy. Stakeholders include representatives from donor organizations, health projects, and the private sector. Information on leadership, power, policy knowledge, interest, and position of stakeholders will be collected through interviews using a questionnaire.

To ensure that definitions and concepts align with the cultural and contextual understanding in Iran, all stakeholders will be consulted to agree on the definitions. A table for stakeholder analysis will be designed in Excel.

Stakeholder analysis will be conducted using Brugha's stakeholder analysis method (15). Stakeholder management will be supported by **Policy Maker 4 software** (http://www.polimap.com).

Policy Analysis: Prospective Approach

The results obtained from the qualitative part of the study will be visualized as a timeline using Walt's policy framework, covering the period from 1991 to 2020, alongside the dietary inflammatory score for each year. Proposed interventions will be prioritized using the multi-criteria decision analysis (MCDA) method.

The prioritized interventions will then be presented as policy options using the Shiffman framework.

Data Collection Tools

The characteristics of the data collection tools and methods are as follows:

1. **Policy Documents:** A document checklist including the title, time, and location of publication, along with items related to the conceptual framework of the research.
2. **Stakeholder Analysis:** An interview guide for stakeholders.
3. **Sample Size and Sampling Method:**

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- Key informants in organizations and institutions will be identified using purposive sampling.
- Snowball sampling will be used to continue identifying additional participants.

4. **Target Population:** The total population of households living in Iran during the period 1991–2020, based on the household income and expenditure survey.

Quality Assurance

All team members will be selected as outsiders to the research context, ensuring they have no prior contact with the participants or the research field. This aspect of the study context will be made clear to all team members. Participants will be purposefully selected from different socio-economic levels and various organizations in the food system to ensure a comprehensive range of opinions. The triangulation method is considered for validation. Two researchers with different perspectives will perform the study, and different sources will be used to collect data. Participants are asked to review and provide feedback on the final results obtained for respondents' answer validation.

Reliability of findings will be ensured by recording, writing, and interpreting data in a structured process. Reaching a consensus on the findings and evaluation of the research is done under the supervision of experts.

Conclusion

This study protocol is the first due to the mixed-methods design and analytical approach for policies in the past, and recommends a priority alternative for the future in Iran. The primary aim of the study is the identification of policy recommendations for decreasing inflammation in dietary patterns in Iran. However, it is expected to yield the following outcomes:

- Calculation of dietary inflammatory index trend in Iran during the past 3 decades
- Estimation of the correlation between the DII score and mortality in 30 provinces of Iran
- Identification of dietary policies to reduce NCD mortality

Privacy and Confidentiality

The research data from the policy analysis will be stored in electronic format for five years. The final result will be shared with all participants through email.

Ethical consideration

The research proposal was approved by the Tehran University of Medical Sciences ethical committee. The findings from the document review will be distributed in a variety of formats: As research reports and presentations to other researchers and policy makers, in academic journals. Key informant information will not be published, and all statements will be recorded unidentifiable. Participants will be asked for their specialized knowledge or general abilities, not personal information. A written consent form will be completed when inviting key informants.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Authors' contributions

Ahmadreza Dorosty Motlagh (ADM) and Amirhossein Takian (AT) supervised, conceived, and supervised the study, commented on various versions of the manuscript, led its intellectual development, and approved the final draft. Ahmad Esmaeilzadeh led and approved the EDII and modified the EDII calculation. Elham Shareghfarid (ES) conducted primary data analysis and drafted the manuscript.

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