

The Relationship Between Food Security and Dietary Patterns Status with COVID-19 in Northeastern Iran: Protocol for a Case-Control Study

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ABSTRACT

Introduction: Food insecurity is described as the inability or uncertainty of having enough food to live an active and healthy life regularly. Coronavirus disease of 2019 (COVID-19) is a highly contagious viral infection that is associated with a high mortality rate due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and/or severe pneumonia. The current research aims to compare food security and dietary patterns with the possibility of developing COVID-19 symptoms in recently improved patients and non-infected cases. **Methods:** This case-control study will be conducted on the men and women aged 20-60 years improved from COVID-19 infection. The cases (n=124) and controls (n=124) were selected according to the eligibility criteria, including recently improved COVID-19 according to the positive COVID-19 PCR test. The groups are matched for age, sex, and body mass index (BMI). The assessments will include anthropometric measurements and general demographic, USDA 18-item food security (18item-FSSM), and 147-item food frequency (FFQ) questionnaires. **Results:** This study received approval from the Tabriz University of Medical Sciences. Participation is free, and a patient can withdraw at whatever point the person feels they are unable to continue. There is no bar to receiving the other health care services of the center. **Conclusion:** This study would be the first assessment of the relationship between food security and dietary patterns status with COVID-19 disease. It may help planners and policymakers manage food insecurity and unhealthy dietary patterns and later increase the immune system and decrease the incidence of COVID-19.

Keywords: Food Security; Dietary Patterns; COVID-19; Iran; Protocol

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INTRODUCTION

A new epidemic of coronavirus infection began in late 2019 in Wuhan, China, named as nCoV-2019 and renamed to coronavirus disease of 2019 (COVID-19) by the World Health Organization (WHO) on February 11, 2020. Acute respiratory syndrome (CoV-SARS), first reported in China in 2002, and middle east respiratory syndrome (CoV-MERS), first reported in 2012, are previous epidemics of CoV, which both began via transmission of the virus from animals to humans, leading to severe pneumonia that in some cases ends with death. Nevertheless, the virus may cause other diseases like acute respiratory distress syndrome, acute heart injury, and RNAemia, which may end with death (1-4). The virus causing COVID-19 transmits so

fast and results in high mortality due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (5). The most frequent presentation is fever, followed by cough and fatigue. However, other presentations include sputum production, headache, diarrhea, shortness of breath, and lymphopenia (4). Nearly one in five cases present severe symptoms, and about 3% of patients lose their lives (6). According to WHO, the annual global incidence of seasonal flu ranges from 3 to 5 million cases, which must be hospitalized. In addition, it claims 290,000-650,000 lives. It is estimated that acute respiratory diseases claimed 2.38 million lives all around the world in 2016 (7). From 1990 to 2017, severe lower respiratory tract infections were the primary cause of death due to sepsis (6). Recently published evi-

dence indicated a relationship between enhanced production of pro-inflammatory cytokines, reactive protein C, enhanced risk of pneumonia, sepsis, acute respiratory distress syndrome, and heart failure (2). COVID-19 pandemic can be considered as the most severe challenge of our era. Among various probable challenges of the COVID-19, one can mention food insecurity. Even before the onset of the pandemic, nearly 280 million individuals had no food to eat, and 110 million were in acute food insecurity (FI) (United Nations, 2020). According to the Food and Agriculture Organization, food security is access to sufficient safe and nutritious foods to address dietary needs and food preferences for an active and healthy life. There is no doubt that lack of enough income pushes families towards cheap, low-nutrient foods, even in high-income nations (8). Therefore, FI is limited/uncertain access to sufficient and safe food or the inability to access acceptable foods in manners that are accepted by society (9). FI ranges from limited ability to feed the family to the inability to afford food products so that there is nothing to eat (10). There are different types of FI, i.e., chronic, seasonal, transient, or at the level of household, region, or nation. FI contains social, cultural, and psychological dimensions; hence, it can be considered a complex, multidimensional issue (11). Noteworthy, FI is not about receiving insufficient energy and nutrients and includes situations in which the person has not the right to choose food, is worried about running out of food, or has fluctuations in food preferences (12). FI can cause a complicated cycle of poorer dietary intake and compensatory overconsumption of poor quality foods, leading to an enhanced risk of metabolic diseases.

Moreover, FI is associated with increased rates of household stress, pushes the person towards a trade-off between food and healthcare services, enhances the risk of abandoning treatment, and results in the declined level of self-management for those suffering from chronic disorders, all-important pathways toward worse metabolic and chronic disease outcomes (13). Hence, FI results in a social disease with various health consequences at both household and individual levels (14). There are evidence indicating the association between FI and chronic conditions and increased risk of chronic diseases. FI leads to lower coping strategies to cope with diseases, which can be attributed to several factors, including not receiving sufficient essential nutrients, impaired mental growth, and psychological and behavioral dysfunction. Lack of financial ability to afford the cost of necessary food products and its mental pressures can result in the development of several health problems and intensify the current illnesses. In addition, FI can cause obesity, high blood pressure, impaired lipids, and blood sugar, as a secondary consequence (15,16). Chronic food shortages lead to nutritional deficiencies, loss of food diversity, and low power modes, leading to impaired physical function. Furthermore, it should be noted that low-cost foods often have high levels of sodium and low levels of potassium, leading to an increased risk of high blood pressure. Meanwhile, poor access to food causes problems in maintaining hydration (17). Also, FI causes both physical and emotional stress, leading to an enhanced level of cortisol, which in turn leads to the accumulation of body fat (incredibly visceral fat). This situation results in increased risk for diabetes and cardiovascular disease (18). The US Economic Search Service reported that Asia has less than half the

prevalence of FI. Based on recent meta-analyses, nearly 49% of Iranians suffer from FI (19, 20). The prevalence of FI and hunger depends on income. In addition, external shocks, such as losing the job, having a seasonal job, having a new child, or not being entitled to a food program, also may contribute to increased risk of FI. Noteworthy, factors like ethnicity, eating habits of different regions, and age and education of the household-head may contribute to FI (21). Various studies, including those performed in Iran, mentioned an association between FI and problems like obesity, declined resistance against disease, hyperlipidemia, diabetes, mental retardation, premenstrual syndrome, acne, depression, gastrointestinal cancer, upper extremities, osteoporosis, starvation, malnutrition, weakened immune system, and declined quality of life (9). Attention towards dietary patterns (DPs) has increased in recent years. First, it should be noted that DPs are conceptually useful to disseminate nutritional recommendations to the public. Also, as DPs consider the internal association among dietary compounds, as well as differences in food intake, following this approach provides a big picture about nutritional intake that can better reflect the disease. Hence, DPs are a technique that can reveal more dimensions of the association between nutritional intake and infectious diseases. Several factors form the DP of a defined population, including geography, socio-economic status, and eating habits. Hence, the methodology of DP depends on the target location and time of the study (22).

There are strong evidence regarding the contribution of nutrition to strengthening the immune system. Several studies indicated that the supply of calories, proteins particularly essential amino acids and vitamins, including vitamins A, B6, B12, C, D, E, and folate. Trace elements like zinc, iron, selenium, magnesium, copper, omega-3 fatty acids, eicosapentaenoic acid, and docosahexaenoic acid have a key complementary role in strengthening the immune system. Poor nutrition, including low consumption of the above-mentioned nutrients, results in declined resistance against diseases, leading to an increased burden of infectious diseases (7). A similar pattern has been observed during the COVID-19 pandemic, as evidenced by the WHO.

MATERIAL AND METHODS

Aim and objectives

The current research aims to compare food security and dietary patterns with the possibility of developing COVID-19 symptoms in recently improved patients and non-infected cases.

Primary objectives

- 1) To investigate and compare food security in cases recovered from COVID-19 and non-infected cases;
- 2) To identify and compare dietary patterns in cases recovered from COVID-19 and non-infected cases;
- 3) To determine the association between food security and COVID-19;
- 4) To determine the association between dietary patterns and COVID-19.

Secondary objectives



This research also aims to identify and compare independent quantitative and qualitative factors (household size, number of living children, employment status, household economic status, being covered by support organizations, receiving food aid, homeownership status, education status, race or ethnicity, and blood groups) in cases recovered from COVID-19 and non-infected cases.

Study design and Setting

We will follow a case-control design, in a 1:1 ratio. The former includes males and females aged 20-60 years with a positive PCR test for COVID-19, and now recovered. The latter includes males and females aged 20-60 years with a negative PCR test for COVID-19 and no symptoms of COVID-19. The study population will be males and females aged 20-60 years living in North Khorasan province, Iran. According to the inclusion and exclusion criteria, we will select participants among those referring to public and private laboratories, employees of offices, factories, administrative departments of universities, and hospitals. There would be no difference between study groups concerning variables of age (every ten years), gender (male and female), and body mass index (BMI) (as defined by the WHO; lean ≤ 18.5 , normal (18.5-24.9), overweight (25-29.9), grade 1 and grade 2 obesity (30-34.9 and 35-40 respectively)). All participants would be selected from similar sites.

Data will be collected using questionnaires, including items on specific and non-specific symptoms of COVID-19 like gastrointestinal symptoms, respiratory symptoms, fever, lack of sense of smell and Taste, and dry cough.

Inclusion criteria

- Pathologically confirmed COVID-19 (group of people improved by COVID-19);
- Age of 20 to 60 years;
- Willingness to participate;
- No history of mental disorders and physical disabilities;
- No COVID-19 infection so far (non-infected group);
- A maximum of 3 months has passed since the onset of COVID-19.

Exclusion criteria

- Being younger than 20 years and older than 60 years;
- Unwillingness to participate;
- Withdrawal;
- Re-infection (for those recovered from COVID-19)
- Presenting COVID-19 symptoms during the study period;
- Not filling more than half of the food frequency questionnaire;
- Those with total daily energy intake of less than or more than three standard deviations from the average energy.

Study variables

Anthropometric evaluations, general demographic questionnaires, USDA 18-item food security questionnaire (item-FSSM18), and a valid 147-item food frequency questionnaire

(FFQ) were considered in this study. Data collection will be performed using face-to-face interviews by a researcher and a senior nutrition expert.

Dietary Evaluations

The usual nutritional intake would be evaluated by the FFQ, which is both valid and reliable (23-25). Data on study variables will be collected by trained dietitians, researchers, and a senior nutrition expert. Intake frequency for each food item consumed during the past year in terms of the day, week, month, and year also will be collected. The reported frequency according to the desired serving size of each food item or household measure will be converted into grams per day (26). Data on food security would be collected using the USDA household insecurity questionnaire (18 items), which is both valid and reliable (27). Its items range from "often true," "sometimes true," "almost every month," "some months," and "yes" and zero score to responses "not true," "does not know or refused," "only 1 or 2 months", to "no." The questionnaire will be filled out using face-to-face interviews by a researcher. A score of 0-2 indicates food security, 3-7 insecurity without hunger, 8-12 insecurity with moderate hunger, and 13 and above insecurity with severe hunger (28).

Anthropometric measurements

A digital scale, stadiometer, and none elastic tape will be used to determine weight (without shoes, with minimal clothing, a 100-g accuracy), height (without shoes, standing, heels against the wall, flat and forward head, and with 0.5-cm accuracy), and waist (with minimal clothing, midway between the last rib and the iliac crest), respectively.

The rest of the evaluations

Demographic, socio-economic, and nutrition status would be evaluated using a demographic questionnaire that includes items on age, education, marital status, occupation, family economic status, number of children, ethnicity, blood type, receiving food aid, health insurance coverage, receiving benefits from public and non-public organizations, medical history, and taking dietary supplements. Also, the questionnaire contains two more items for those in the intervention group; i.e., time since onset of the disease and recovery status (i.e., recovery, home quarantine, hospitalization, and recovery in the hospital, or hospitalization and recovery in the intensive care unit).

Statistical analysis

Data analysis will be administered using SPSS version 16. The findings would be described using mean, and standard deviation. The Kolmogorov-Smirnov test will be used to evaluate the normality of quantitative data. Inter-group comparisons would be performed using the independent t-test and Mann-Whitney test for abnormal quantitative variables. Chi-square and Fisher tests will be used to compare the distribution of qualitative variables between the study groups. Statistical significance was considered when p -value < 0.05 .

The Sample size

Initially, a pilot study would be performed to increase familiarization of the research team with the research context, how patients respond to items, necessary revisions in data collection tools, determining the sample size, and the accuracy of the study. Based on the pilot study on 13 cases recovering from

COVID-19 whose positive PCR test was confirmed by Esfarayen Central Laboratory, the percentage of food insecurity was 69% ($P_2 = 0.69$). In addition, according to the pilot study on 13 cases with no history of COVID-19 infection and with positive PCR, the prevalence of food insecurity was 46% ($P_1 = 0.46$). Using the following formula and by considering 5% dropout, 95% power, and 95% confidence interval,

the sample size was determined as 248 ($n=124$ in each group):

$$n = \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2 [P(1-P)]}{(P_1 - P_2)^2}$$

$$RR \approx OR = \frac{P_2}{1 - P_2}$$

$$\bar{P} = \frac{P_1 + P_2}{2}$$

RESULTS

This study received approval from the Tabriz University of Medical Sciences. Participation is free, and a patient can withdraw at whatever point the person feels they are unable to continue. There is no bar to receiving the other health care services of the center. Data collection and analysis are expected to conclude by July 2022.

DISCUSSION

This study is the first case-control interview-based study to examine the food security status and dietary patterns of individuals in the case group (improved by COVID-19) and the control group (individuals who have never had a COVID-19 infection). The practical purpose of this project is to provide information to planners to design the next steps in reducing food insecurity, modifying the diet, and using the appropriate diet, boosting the immunity system, reducing the incidence of COVID-19 infection, and perhaps other infectious and viral diseases. The study's strengths are case-control design, protocol publication, and the assessment of dietary patterns and food security status. The study's limitations are self-reporting of dietary intakes, and lack of cooperation of some patients in the end, which may lead to patients being replaced.

CONCLUSION

This study would be the first assessment of the relationship between food insecurity and dietary patterns status with COVID-19. It can help planners and policymakers manage food insecurity and poor and inadequate nutritional intakes. It may boost the immune system and decrease the incidence of viral or bacterial infections, especially COVID-19.

ETHICAL CONSIDERATIONS

This study is being conducted with the approval of the ethics committee of the Tabriz University of Medical Sciences (Ethical Code: IR.TBZMED.REC.1399.1053). A written informed consent form (in Persian) is being obtained from all the participants. Participation is free, and a patient can withdraw at whatever point the person feels they are unable to continue. There is no bar to receiving the other health care services of the center. The personal information of participants will be kept secret before, during, and after the study.

CONFLICT OF INTERESTS

There is no potential conflict of interest for research, authorship, and publication.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available from the corresponding author at reasonable request.

ABBREVIATIONS

COVID-19; Coronavirus disease of 2019, SARS-CoV-2; severe acute respiratory syndrome coronavirus 2, BMI; body mass index, FFQ; food frequency, WHO; World Health Organization, MERS; middle east respiratory syndrome, DPs; dietary patterns.

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Author Contribution: SBF, MDM and BPG conceived and designed the study. SBF and MBF participated in the organization of the activities. SBF, and MBF managed the activities and collected the data. SBF analyzed and interpreted the data. SBF, MDM, MBF, MP, and BPG drafted the article. SBF, MDM, MBF, MP and BPG revised the manuscript critically for important intellectual content. All authors read and approved the final article.

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