



# INVESTIGATING THE INFLUENCE OF COVID-19 QUARANTINE ON HEALTH-RELATED DETERMINANTS AMONG SAUDI ADULTS: A QUALITATIVE STUDY

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## ABSTRACT

After the WHO declared COVID-19 a global pandemic, most countries resorted to declaring a period of lockdown to diminish the spread of the coronavirus. Lockdown and curfew were imposed in Saudi Arabia on March 23, 2020 for about three months. This study aimed to investigate the impact of COVID-19 lockdown on health-related determinants of eating behaviors and physical activity in Saudi Arabia using the Social Cognitive Theory (SCT). To gather information from the participants, semi-structured interviews with open-ended questions were used. A total of 41 interviews were conducted (20 males and 21 females). Most women expressed concern about gaining weight as a result of a rise in sweets and snacks, while fewer men expressed concern about weight due to lack of physical activity. The most popular foods purchased were fruits and vegetables aiming to improve health and boost immunity. Yet, increased snack and high-calorie food intake were the most frequently recorded. Most responses were marked by a high awareness about healthy eating. During the lockdown, physical activity declined, causing participants to become more stressed. Reliance increased on home-cooked meals and decreased on restaurants. The COVID-19 lockdown resulted in several changes in eating habits, including increased intake of snacks, sweets, fruits, vegetables, and home-cooked meals.

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## Introduction

The World Health Organization (WHO) was alerted on 31 December 2019 to the occurrence of unexplained pneumonia cases detected in Wuhan, China [1]. A novel coronavirus disease (COVID-19) was eventually identified [2]. On 30 January 2020, Emergency Committee WHO declared COVID-19 acute respiratory infection to be an international health emergency [3]. In Saudi Arabia, the first case of COVID-19 was detected on 02 March 2020 [4]. As of preventive procedures, on 09 March 2020, the Saudi government announced the suspension of schools, universities, and educational institutes across the country, and distance education was initiated. In addition, to counteract the spread of the virus, lockdown and curfew were put into place on 23 March for about three months [5]. The curfew period was applied at different stages with certain times of confinement according to the need, especially in the cities that observed an increase in the rate of COVID-19 cases, including the city of Jeddah [6, 7]. The closure was required of all non-essential public places, stores, businesses, and recreational facilities. Movement in the street was restricted to health and police authorities as well as those whose work was approved to continue in this prevention period. The curfew restriction was dropped to everyday life by the end of June 2020 to the post-lockdown period, with total commitment to preventive health instructions and social distancing. The COVID-19 lockdown imposed sudden and drastic changes in daily routine, including eating behaviors and physical activity [8]. Different studies investigated the effect of COVID-19 on dietary behaviors and lifestyle changes [9-11]. Research has shown that the period of quarantine was associated with disrupting nutritional and health behaviors such as weight gain, frequent snacking, decreased physical activity, and increased stress and anxiety [12-15]. Physical isolation of staying at home for a prolonged time and being away from friends and other important ones certainly impact psychological status [16]. Another factor is that being trapped at home and having restricted mobility, especially for children, can be stressful for all family members [17]. Stressful situations are associated with behavioral reactions as coping strategies such as overeating or undereating foods [18, 19].

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The Social Cognitive Theory (SCT) highlights behavior in a reciprocal model and emphasizes the importance of personal, social, and environmental domains and their interactions to produce a particular behavior [20, 21]. Research studies, however, on SCT determining health behaviors using a qualitative approach are considerably rare [22].

In the current study, SCT was utilized to understand better multilevel factors influencing peoples' behaviors during COVID-19 lockdowns. The present study aimed to examine qualitatively the impact of COVID-19 lockdowns on health-related determinants of eating behaviors and physical activity applying SCT.

## Materials and Methods

### *Study Design and Recruitment*

The present study used a qualitative research design as it provides rich data and helps in gaining a deep understanding of people's experiences. Semi-structured interviews with open-ended questions were developed based on the SCT constructs (i.e., behavioral capability, social support, self-regulation, self-efficacy, environmental mediator, and outcome expectation) as applied to examine the impact of COVID-19 on people's eating behaviors and physical activity during the time of quarantine in Saudi Arabia. Announcements on social media platforms invited people to participate in the study. Participation was completely voluntary, and participants had the right to withdraw at any time from the study. The study was conducted during COVID-19 lockdown between end of May and the first two weeks of June 2020 in Jeddah, Saudi Arabia. All participants included must be Saudi and aged 18 years and above. Participants were excluded if they had diseases that required a specific diet, such as diabetes.

### *Data Collection*

Prospective participants received message notifications informing them of the research purpose and methods. Only people who agreed to participate and gave their consent for inclusion in the study were contacted for potential participation. Once potential participants were identified, the time and date convenient for participants and researchers were arranged for the interview.

All interviews were conducted individually via phone. The research team, which consisted of the authors of the study, was trained in qualitative research and conducted 41 in-depth interviews. At the beginning of the interview, participants were given an overview of the topic to be addressed, as well as the reasons for conducting the study and the interview process and procedures. Each interview lasted approximately 40–60 minutes. When necessary, probing questions were used to encourage respondents to provide more details or explain responses. After each interview, participants were asked to complete a brief online questionnaire, which included questions about their demographics, height, and weight.

### *Data Analysis*

Data collected from the short questionnaire were analyzed using SPSS Statistics 24 to obtain the descriptive statistics of the study sample. Descriptive statistics, including frequencies, percentages, and means, were performed. A hybrid approach of deductive and inductive thematic analyses was used [23, 24]. The deductive process was demonstrated using a script guided by SCT and priori constructs based on the theory. For the inductive process, a coding list for recurrent themes and subthemes was created throughout the transcript [25]. Similar codes were derived from keywords or phrases that often appeared in the dataset. All interviews were transcribed and translated into English and double-checked by two researchers. The interview transcripts were organized for analysis using the ATLAS.ti 9.0 qualitative computer software.

To ensure trustworthiness, transcripts were reviewed several times by two researchers, and key themes and subthemes were independently generated. The researchers discussed uncertainties and controversies till they reached a consensus. The research was grounded in examples by providing direct quotes to support the interpretations and conclusions achieved.

## Results and Discussion

### *Participants Characteristics*

In this study, a total of 41 interviews were conducted. Participants were between the ages of 21 and 50 years old. The body mass index (BMI) of the participants was calculated from self-reported height and weight. The mean BMI was 26.5 K/m<sup>2</sup> ranging between 18.8 and 42.5 K/m<sup>2</sup>. The sample consisted of 20 males and 21 females. Across the sample, the educational level of most participants was at the university level 65.9% (n=27). The majority of the participants were employees, 36.5% in the governmental sector and 26.8% in the private sector, whereas 19.5% indicated being unemployed. Of the respondents, 70.7% were married (n = 29) and 26.8% were single (n = 11). For the income level, 34.1% indicated an average income of 10,000 to 20,000 SR/month. **Table 1** provides sociodemographic information for the study participants.

**Table 1.** Demographics Characteristics of Study participants

| Variable           | (n = 41)         |
|--------------------|------------------|
| Mean Age (Min-Max) | 34.9 (21-50)     |
| Mean BMI (Min-Max) | 26.5 (18.8-42.5) |

| <b>Gender</b>            |            |
|--------------------------|------------|
| Male                     | 20 (48.8%) |
| Female                   | 21 (52.2%) |
| <b>Education level</b>   |            |
| High school              | 5 (12.2%)  |
| University               | 27 (65.9%) |
| Higher education         | 9 (22.0%)  |
| <b>Employment Status</b> |            |
| Student                  | 6 (14.6%)  |
| Unemployed               | 8 (19.5%)  |
| Government employee      | 15 (36.5%) |
| Private sector employee  | 11 (26.8%) |
| Retired                  | 1 (2.4%)   |
| <b>Marital Status</b>    |            |
| Single                   | 11 (26.8%) |
| Married                  | 29 (70.7%) |
| Divorced                 | 1 (2.4%)   |
| <b>Income</b>            |            |
| Less than 5000           | 9 (22.0%)  |
| 5000-9999                | 9 (22.0%)  |
| 10000-20000              | 14 (34.1%) |
| More than 20000          | 9 (22.0%)  |

n= number; %= percentage; BMI= body mass index

### *Behavioral Capability*

#### *Concerns of Weight and Body Shape*

Most women reported concerns about weight gain, as the consumption of snacks and sweets increased considerably during quarantine. "Yes, I spend a lot of time worrying about what I eat and how much I weigh, because weight is increasing and eating is increasing." Female.

They have raised fears about being overweight due to decreased mobility and physical activity as well as being restricted at home. "I'm afraid of gaining weight and changing my body shape. Since we are not moving as much during this time, I stand up in front of the mirror every day and look at my body." Female.

While some sought to have the opportunity to reduce weight during the quarantine period since there were no social gatherings, others found it difficult as they stayed at home with the family and had a variety of foods available. "I frequently believe that I must eat well in order to lose weight, but I am unable to do so due to several distractions at home, and it is difficult for me to refrain from eating." Female.

Men also expressed concerns about weight but much less than women. Their concerns were primarily due to a lack of physical activity and long hours of staying at home. "With the lack of movement during quarantine, I consider how to maintain the ideal weight." Male. Many men emphasized the importance of food in promoting health and well-being. "Of course, I'm thinking about food this time because I want to remain safe and boost my immunity to protect myself from coronavirus." Male.

#### *Choices of Foods*

When asked about the most common types of foods purchased during quarantine, the majority of participants mentioned fruits and vegetables to be the most common. Reasons reported for having fruits and vegetables as a priority to buy during this period included being healthy foods, containing vitamin C, maintaining health, and strengthening immunity. Other advantages listed by females included having healthy skin and maintaining a healthy weight. "I Buy fruits and vegetables because they have no calories, so no matter how much I consume, I will not gain weight, unlike if I eat chips." Female.

Males mentioned other benefits of fruits and vegetables as sources to promote energy. "Vitamin C is found in fruits and vegetables, which helps to boost immunity and energy, particularly since we are inactive during the quarantine period." Male. Chocolate, crackers, chips, and ice cream were also frequently mentioned especially by parents for their children's treats. Participants listed other foods such as poultry, meat, and fish as essentials for meal preparation.

#### *Changes in Eating Behaviors*

The most frequently reported change among participants was the increased snack consumption. Staying at home for long periods, being up late at night, and feeling bored and stressed were all cited as explanations for increased food intake. "After dinner, we have coffee and desserts, we stay at home, and we have a long time." Female.

Some participants mentioned an increase in food consumption, especially high-calorie foods, at the beginning of quarantine. Yet, after almost two months of quarantine, they started to go back on track. *"At the beginning, we spent a lot of time eating snacks and sweets, three weeks ago (two months of quarantine), I started to pay attention to my diet."* Female.

The vast majority of women stated that they prepared their meals at home. Some mothers revealed that having their work suspended gave them more time to cook. *"As a working mom, I used to prepare one meal, but now that I have more time, I can prepare a variety of meals."* Female.

Some participants mentioned that they were eating healthier than before, as they saw the crisis as a chance for change. *"The time of lockdown had a positive impact on me. I discovered that food affects human health."* Female.

A few people did not change their dietary habits because they were committed to a balanced diet before the pandemic. *"My diet hasn't changed during the quarantine because I already adopted a healthy lifestyle."* Male.

#### *Awareness of Healthy and Unhealthy Eating*

Most participants characterized healthy eating as consuming more vegetables, fruits, protein, and fiber while consuming fewer fats, oils, and sugar. Many people considered healthy eating to be eating home-cooked and prepared meals. *"There is no healthy food as home-cooked food."* Male.

Furthermore, some participants characterized healthy food as consuming natural, and fresh foods without artificial additives as well as eating in moderation. *"Healthy eating is when you consume small amounts of food to avoid gaining weight."* Female

When asked about unhealthy eating, the most popular response was eating fast food or eating out at restaurants. Fried foods and high-sugar foods were among the other responses. *"All eating outside home is unhealthy."* Male.

#### *Social Determinant*

##### *Family Role*

Women's social influence was deduced by the perceptions of their husbands and children. Children's influence on their mothers at this time was observed as increased demand for treats, such as candies and chips. *"In quarantine, my children always want to eat sweets, chips, and chocolate even though they didn't normally ask for them."* Female.

Some parents reported being more flexible when their children feeling bored, so they were compelled to give them chips, candies, and other sweets. Two mothers found their children to be gaining weight during this period. *"With the kids these days, it's like, 'We're bored, let's eat,' rather than 'We're bored, let's go out.'"* Female.

Some wives reported an increase in the consumption of food because they stayed at home with their husbands most of the time. *"Before quarantine, we used to eat three meals a day, but now we sit with each other and eat more."* Female.

Most husbands mentioned the wife as being the most influential. The wife's supportive role included cooking healthy meals at home and providing helpful nutrition information. *"My wife helps me to eat healthily and avoid foods that are harmful to my wellbeing."* Male. The majority of unmarried men reported having no social effects on their eating behaviors.

#### *Self-Regulation*

##### *Dietary Behaviors*

The main causes of overeating during quarantine, according to many participants, were stress and anxiety. Others admitted that they could not stick to healthy eating for a long time and that planning and preparing healthy food took time. *"Healthy eating always needs time to prepare."* Male.

Participants also stated being unable to curb their urge to eat sweets during the lockdown since this form of food was readily available to them at home. *"I find it difficult to avoid treats such as sweets when they are readily available at home, so I eat them. Almost every day, I prepare desserts for my family, which I then share with them."* Female.

Some participants mentioned that people they lived with could be either barriers or supporters of healthy eating. It was challenging to maintain healthy eating habits without their active involvement. *"You'll need someone to help you prepare healthy meals and make healthy food choices."* Male.

#### *Physical Activity*

Because of the lockdown, the majority of respondents said their physical activity had declined significantly. Gyms were closed, and people were unable to go for walks outside. *"My physical activity was excellent before this phase, but it has sadly declined due to the precautions not to leave the house during this time."* Male.

Others who used to go to the gym before COVID-19 said it was difficult to sustain physical activity after gyms closed; however, they began to participate in physical activity by purchasing gym equipment and exercising at home. *"I used to go to the gym before Corona, but after Corona and the closure, I purchased sports equipment and fitness items for myself to use at home and improve my skills."* Female. Several people took advantage of the government's one-hour walking permission during the 24-hour lockdown that was restricted to the neighborhood zone only.

Some of those who were inactive before COVID-19 expressed concern about their weight gain and resolved to begin exercising to lose weight. Others found that they had more free time to exercise during quarantine than they had before. *"I was not active prior to lockdown, but my weight started to increase after that, so I began to exercise to lose weight."* Female.

#### *Self-Efficacy*

*Controlling Eating*

When asked whether participants thought they were losing control of their eating as a result of the quarantine, almost half of the women said they did. *“During quarantine, I’m experiencing a greater sense of loss of control, as I used to work and occupy myself with work before corona, but now I don’t work, and food is always in front of me.”* Female.

The majority of men said they had control over their food consumption, with only a few saying they felt out of control at times. *“Currently, the level of control is very high, particularly because you have no social responsibilities that prevent you from sticking to your diet”* Male.

*Environmental Determinant*

*Home Environment*

During quarantine time, the majority of participants ate home-cooked meals, and families typically ate most of their meals together. Many families were determined to avoid eating from restaurants as a precaution against the infection. Therefore, mothers were concerned about preparing meals and snacks and making healthy food choices for their families. *“My thoughts are currently focused on children’s meals. It is the most thing I think about during the quarantine. What should I prepare for the children?”* Female.

Most women reported that they were cooking more meals than they did prior to quarantine. They also reported preparing new dishes to satisfy family members who might miss some of their favorite restaurant meals. *“I am now preparing more dishes at home because I do not have work during this period, so I cook more and make more types of desserts that I have never done before.”* Female.

Many men reported that their fast-food consumption had decreased considerably compared to that before quarantine *“It is becoming rare to buy from fast foods restaurants, and this is good thing.”* Male.

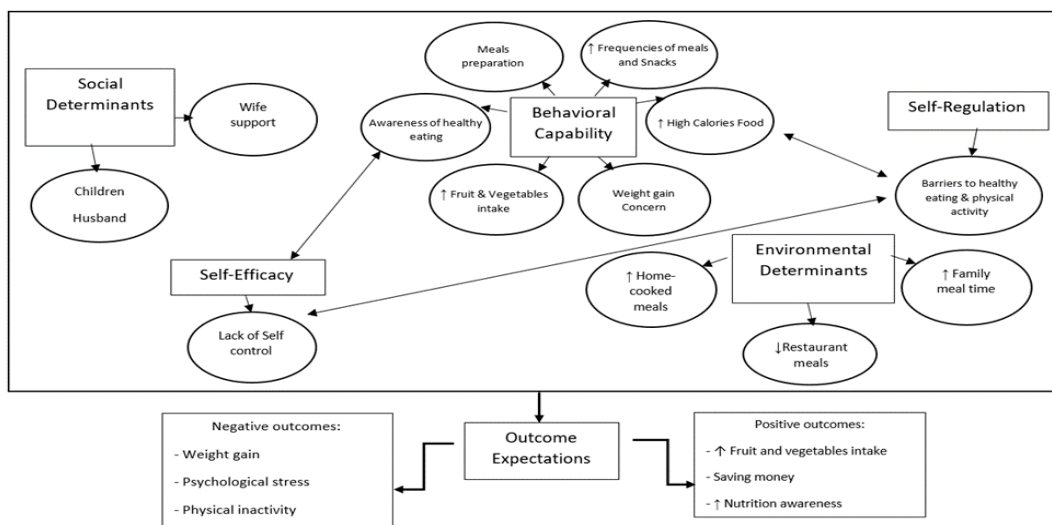
*Outcome Expectations*

Among the positive outcomes expected by participants as a result of changes in dietary habits during quarantine was to eat more of home-cooked meals and avoid fast foods which helped to decrease spending money on restaurants. The awareness of the value of consuming healthy foods such as fruits and vegetables to improve health and boost one’s immune system was increased. *“A new way of living, different grocery shopping, and healthier eating habits, all of which have a positive impact on our health and allow us to save money on restaurant meals.”* Male. *“Strengthening our immunity became a priority for us”* Female.

In terms of the negative outcomes, some participants expected to gain weight because they were eating more than normal and were physically inactive due to spending much of their time at home and watching TV. Others were worried about the negative effect of psychological stress on them and their children. *“In reality, I’m afraid of gaining weight and of being infected with coronavirus, and I’m physically exhausted from sitting in the house.”* Female. *“During this time, unhealthy eating increased, as did the amount. These are attributed to free time and TV viewing.”* Male.

*Theoretical Framework*

According to the SCT a composite framework of factors influencing eating behaviors and lifestyle was developed based on content analysis of the interviews (**Figure 1**). The framework emphasizes the interaction of multilevel of the identified personal, social, and environmental determinants for understanding factors influencing behaviors in Saudi people during COVID–19 quarantine.



**Figure 1.** Conceptual framework of health-related determinants during COVID-19 quarantine based on the Social Cognitive Theory (SCT)

To the best of our knowledge, this is the first study to examine the impact of COVID-19 quarantine on health-related determinants on a sample of Saudi people using a qualitative approach. The current study utilized the constructs of SCT to better understand the factors that influenced health behaviors during the lockdown in Saudi Arabia. The findings highlight the relevance of using SCT in health behaviors that are greatly influenced by interrelated factors which reflect individual, social, and environmental dimensions [26].

One of the most frequently mentioned changes was the increase in the number of snacks, and thus an overall increase in food consumption. Reasons reported for this increase included being restricted to stay at home for a long time, experiencing higher boredom, feeling pressure from catching the disease, staying up too late, and eating after dinner.

Though quarantine is necessary to control the spread of the virus, self-isolation and affected the emotional status of people, leading to potential disturbances in eating behaviors [27-29]. Turning to comfort eating is one of the potential responses to negative feelings of pressure, anxiety, and boredom [30, 31]. When examining self-regulation as a determinant of the changes in healthy food habits during this period, participants experienced stress and anxiety due to fear of infection and home restriction. Consequently, this influenced their eating habits and led them to overconsume calorie-dense foods. Many men in the study reported being able to control overeating habits, while a lot of women reported having difficulty doing so. In line with a previous study, females experienced significantly more psychological distress than males [32].

Some participants whose food intake increased during quarantine, and those who gained more weight, planned to return to a more balanced food intake. Others desired to take advantage of the lockdown to lose weight, as presence of social settings was one of the barriers to weight loss. However, the majority of participants expressed their concerns about weight gain and body shape, contributed by the increase in food intake and decrease in physical activity during quarantine. This was reported more frequently by women than by men. Similar results showed that women were more likely to be anxious about body shape and weight, especially during stressful times [33-35].

Nevertheless, there has been a remarkable increase in interest among participants in improving food choices to be healthy and to strengthen immunity in order to combat the virus. This was evident in food choices as most of participants indicated their willingness to buy fruits and vegetables, especially those that contained vitamin C. Mothers ensured to provide their children with natural sources of vitamin C as well. This indicated the sample's awareness of healthy food choices to maintain health in such an outbreak.

Participants were consciously aware of healthy eating as they defined it as containing vegetables, fruits, protein, fiber, and less fat and sugar. Many participants defined it as eating home-cooked food, and they also mentioned that any food that was not prepared at home was unhealthy. Eating out involves consuming food that is usually high in calories from fat and sugars [36], and is associated with weight gain [37]. While frequent consumption of home-cooked meals has been associated with improved diet quality [38]. From many participants' perspectives, their eating habits are now healthier than they were before the lockdown. This could be pertaining to the fact that most participants were eating more home-cooked foods, which they defined as healthy eating.

Social pressure has a great effect on eating habits; children and husbands were the most influential people for women during the lockdown. It was evident that quarantine had a great influence on children [39, 40]. Parents in this study indicated that their children were experiencing higher boredom during quarantine, which made them turn to food and desire sweets and other palatable foods. This drove some parents to be more flexible with offering high-calorie foods such as sweets and chips. Moreover, the closing of schools, sleep pattern disturbance, and being away from friends can cause children to experience anxiety and distress [41]. Studies have shown that children are most prone to weight gain during the summer months when they are out of school [42-44]. In our study, an increase in children's weight during quarantine was reported. Some mothers, who had more time due to suspended work were able to cook and prepare meals more often. An increase in making desserts at home was also reported by mothers in the study.

For married people, staying together most of the time led couples to stay up late and snack more frequently. In line with other research, people who live together drive the demand for food, usually leading to disrupted eating practices [45]. The social influence on married men was mostly from wives in terms of encouraging family to eat healthy and caring about preparation of healthy foods. In accordance with previous research, our findings showed the roles of wives in supporting healthy food choices for their husbands' health [46]. Previous studies have shown that social factors play a central role in human behaviors [47], and thus it is important to target this factor in future intervention research aiming to improve healthy lifestyles.

When examining the environmental factors as determinants of changes in eating behaviors, it was found that majority of participants were concerned about food safety and fear of infection from ordering takeaway foods. Participants stated that it was safer to eat food prepared at home than to risk their families. Consistent with existing research, this was due to their responsibility and deep concern for their well-being and family's health during this crisis [48]. Avoiding restaurant meals drove women to cook similar meals to fulfill their family members' desire to eat from outside. This can be a positive outcome, as cooking at home found to be associated with more nutritional values, quality of the ingredients, and normal body weight.

Regarding the impact of COVID-19 period on the patterns of physical activity, variations were observed among participants and even for the same person. Most participants indicated a decrease in their daily physical activity. Many men stated a desire to increase physical activity compared to women. This variation may be due to gender differences in responses to surrounding factors and determinations. On the other hand, people whose work was suspended found the time to engage in physical activity at home during quarantine. One positive side of quarantine noted was that it allowed some participants to engage in physical activity, especially those who already had a previous intention but had barriers such as limited time or social barriers. Others

started to engage in physical activity to lose weight gained during home confinement, especially utilizing the one-hour governmental permission to walk outside. Physical activity has great benefits on human health and in enhancing immunity functions; however, it was noted that participants sought to improve their health by increasing the consumption of fruits and vegetables, but most of them did not relate optimizing immunity by optimizing their activity.

The findings of this study suggested that people's habits varied during home confinement. Some were committed to a healthy lifestyle before COVID-19 and were able to continue on that during quarantine. This is supported by studies showing the effectiveness of goal setting in sustaining health behaviors and preventing relapse. There were others whose eating and physical activity behaviors were affected during the lockdown in which there was overconsumption of food and reduction in physical activity as compared to the period before lockdown. There were also people who found lockdown as an opportunity to improve their behaviors for the better.

Moreover, it appeared that women were more vulnerable to the influences of the pandemic and were involved in unfavorable health behaviors, including lack of self-control for overeating, increased consumption of high-calorie foods, and low physical activity. The negative outcome expectation that participants identified included concerns of gaining weight. The bright side of quarantine revealed by some participants was gaining knowledge about healthy lifestyle, consuming homemade food, having more family meal time, and saving money.

The findings of this study are important because it provides a comprehensive and in-depth approach by using the SCT to understand the changes in the behavior of Saudi individuals. It also drew researchers' attention to the consequences of COVID-19 quarantine on health outcomes. Undoubtedly, physical inactivity and poor diet intake, including high sugar intake, are risk factors contributing to serious health problems. Unfortunately, the continuation of this pandemic could have long-term outcomes on people's health. Therefore, urgent intervention trials are needed to help people modify their behavior to healthier ones and prevent further health complications.

The limitations of the study included that with the qualitative research approach, this study focuses on generating a rich understanding of participants' experiences in a particular context, which is different from quantitative research that often focuses on generalizing results under certain circumstances. Participants were volunteers and perhaps were interested in the topic, which could have resulted in a selection bias. Additionally, many participants' work was suspended during the COVID-19 lockdown. Findings might have different indications with different working status. However, this study is the first to provide deep understanding of health-related determinants of eating behaviors and physical activity during lockdown in Saudi Arabia utilizing SCT multilevel determinants of health behaviors as individual, social, and environmental domains.

## Conclusion

The lockdown period during COVID-19 outbreak affected people's habitual activities, resulting in different changes in their eating behaviors and physical activity. Changes as described by most participants were identified in different dimensions. At the individual level, intake of fruits and vegetables increased; yet, there was an increase in the consumption of snacks and sweets as well as a decrease in physical activity. At the social level, husbands and children were the most influencing people for women. Avoiding takeaway and restaurant meals as well as increasing the consumption of home-cooked meals and family meal time were identified as part of the environmental dimension.

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**Ethics statement:** Informed consent was obtained from participants prior to performing the interviews. All procedures conducted in the study were in accordance with ethical standards Institutional and/or National Research Committee and with Declaration of Helsinki.

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