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## STUDY PROTOCOL

# COVID-19 and Menstrual Cycle Changes: A cross-sectional study from Egypt and Saudi Arabia

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### ABSTRACT

*The aim of this study is to determine menstrual changes in females following COVID-19 infection, and to evaluate female perception about the effect of COVID-19 on their menstrual cycles. This is a cross-sectional survey-based study, so a convenience sample of 1000 Egyptian and Saudi women previously infected with COVID-19 will be recruited to share in this study. Women will be asked to fill in the study questionnaire online and data will be analyzed to evaluate cycle changes' nature, duration and measure women's perception about COVID-19 effect on their cycle. This study represents one of the few studies across two countries that seeks to investigate the changes in menstrual cycle following COVID-19 infection and women's perception about changes effects on their cycle. Researchers hope that the current study will lead to better insights regarding the nature and duration of changes, measure woman's perception.*

*Keywords: COVID-19, Menstrual Cycle, IQR, VIF*

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### INTRODUCTION

Menstrual cyclicity is an overt sign of health and fertility. Menstrual characteristics are not static, and variability exists month to month across an individual's lifespan [1]. The International Federation of Gynecology and Obstetrics classifies a variation in cycle length as normal if less than 8 days. During the previous two years, the entire world was terrified by the COVID-19 pandemic, which claimed millions of lives and had long-term consequences. People who had recovered from COVID-19 infection were concerned about loss of smell, taste, and appetite, among other symptoms. Recently, there have been scientific reports and even social media discussions that a significant number of females infected with COVID-19 have experienced changes in their menstrual cycle [2]. In general, the menstrual cycle is a complex interplay of the hypothalamus, pituitary, ovaries, uterus, prostaglandins, and neuroendocrine factors. Menstrual disturbances can thus be caused by a disruption in any of these interactions [2].

### Objectives:

#### Primary objective

To determine menstrual changes in females following COVID-19 infection, and to evaluate female perception about the effect of COVID-19 on their menstrual cycles.

#### Secondary objectives

To evaluate the nature of menstrual cycle changes following COVID-19 infection

To detect the duration of menstrual cycle changes

To evaluate women's perception about the effect of COVID-19 on menstrual cycles

#### Study questions

The current study is anticipated to give better insights about the nature and duration of menstrual changes, measure woman's perception. Researchers will also try to analyse the data with a view of developing a predictive model for proper accommodation with the reported changes. Researchers formulated study questions in order to articulate study work as follows:

What are the changes experienced by Egyptian and Saudi women following infection with COVID-19?

What is the duration of experienced menstrual changes?

What is women's perception about the effect of COVID-19 on their menstrual cycles?

## **MATERIAL AND METHODS**

**Design:** A cross-sectional design will be used for conducting the current study

**Setting:** The study will be conducted across two countries: Egypt and Saudi Arabia by distributing the study survey through different social media to facilitate women's participation.

**Sample size:** The sample size will be calculated using Epi Info (2000) program depending on previous studies available, the most suitable literature was [2]. Based on this data sample size was calculated at: Power 80%, Confidence level 95% and Margin of error 0.05. Accordingly, the calculated minimum sample size required was 1000 women with Egyptian to Saudi women ratio 1:1 so 500 participants in each group.

**Inclusion criteria:** adult females Egyptian and Saudi who had infected with COVID-19, accept to voluntary participate in the study through filling in the questionnaire.

**Exclusion criteria:** Women who didn't had COVID-19, those who refused to participate in the study.

### **The characteristics of participants and how the sample will be selected:**

A convenience sample of women will be invited to participate in this study by distributing the survey through different social media (Facebook, WhatsApp, Instagram and Snapchat). The study survey will take about seven minutes to be filled. Women will be informed that participation is voluntary, their data will be secure and used for study purpose only then represented through numbers not names. They will be asked to provide electronic consent before filling the survey through choosing agree or disagree button.

### **Survey instrument development and validation**

Based on previous available research, an authenticated questionnaire assessing the effects of COVID-19 on menstrual changes will be developed [3]. The questionnaire will be divided into four sections, the first assesses participants' demographic data and information. The second section determines the participants' medical history and data. The third section evaluates the menstrual cycle changes that occurred following COVID-19 infection (duration and nature). The final domain includes females' perceptions of the impact of COVID-19 infection on menstrual cycle changes.

The questionnaire will be translated into Arabic and then back into English before being distributed in Arabic to participants, as Arabic is the mother tongue of the recruited women. Following that, the questionnaire will be piloted to evaluate its structure, clarity, length, and overall impression. A group of experts in the field will test the draft questionnaire for face and content validity.

### **What outcomes will be measured**

Changes experienced by Egyptian and Saudi women following infection with COVID-19, duration of experienced menstrual changes and women's perception about the effect of COVID-19 on their menstrual cycles.

**Data management plans:** Women's data will be entered and stored on Google forms, extracted using excel sheet then will be analyzed using the statistical package for social sciences SPSS (IBM SPSS Statistics, version 22.0, Chicago, Illinois).

**The type of data and statistical analyses planned:** Descriptive analyses will be presented as median  $\pm$  interquartile range (IQR) for continuous variables, while frequency and proportions will be used for categorical variables. Simple linear regression will be carried out to screen the independent variables that affect women's perception. Variables that will be found to have P-value  $< 0.25$  will be entered into multiple linear regression analysis. Variables will be selected after checking their independence, where tolerance values  $> 0.1$  and Variance Inflation Factor (VIF) values  $< 5$  will be selected to indicate the absence of relation between the independent variables in regression analysis. In the multiple linear regression analysis, variables that will be independently affecting participants' perception will be identified.

**Ethical considerations and declarations:** The ethical committee at Faculty of Nursing, Menofya University, Egypt provided Institutional Review Board (IRB) approval at (FON, MU:7/5/2022). The World Medical Association Declaration of Helsinki guidance will be followed in the study [4]. Jouf University guidelines for conducting researches on human beings will be also considered. Women will be informed that participation is voluntary, their data will be secure and used for study purpose only then represented through numbers not names. They will be asked to provide electronic consent before filling the survey through choosing agree or disagree button.

**The status and timeline of the study:** The study is expected to commence in January 2023. It is expected that it will require one month for data collection to be completed.

**Discussion:** This study is the first large one to be conducted across the two selected countries to evaluate the menstrual changes and women's perception about the pandemic effect on their menstruation. Dealing

with the large amount of data may need more time for analysis and categorization. The study will be published in a peer-reviewed academic journal once it is completed and analysed.

**Authors' contributions:**

Conceptualization: Amera Rashed, Nevin Adel Amer

Investigation: Amera Rashed

Methodology: Nevin Adel Amer

Project administration: Amera Rashed

Writing – original draft: Nevin Adel Amer

Writing – review & editing: Amera Rashed and Nevin Adel Amer

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