

# The effects of the COVID-19 pandemic on mental health

<b>Submission date</b> 09/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/12/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/01/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

On 11 March 2020, the WHO declared the novel coronavirus (SARS-CoV-2) infection pandemic. Along with the increased pressure on the medical system, the spread of SARS-Cov2 infection has generated multiple economic and social effects on society. Fear of being infected, the measures of social distancing (reducing social contact, limiting recreation, etc) imposed to limit the transmission of the virus, along with financial instability generated by job loss, are the main causes of mental health damage during the COVID-19 pandemic.

In this context, family physicians, along with other medical professionals, play an important role in managing psycho-emotional changes as part of the pandemic response.

In clinical practice during the pandemic, the monitoring of psychosocial needs and the support provided to patients during direct (face to face) meetings have been greatly reduced due to isolation/quarantine measures at home and due to restricted access to services. caused by the rapid spread of SARS-CoV-2 virus infection. In this context, it is necessary to develop methods for remote evaluation of patients by family doctors through telephone consultations and/or communication via the Internet.

The aim of this study is to assess the impact of the COVID-19 pandemic on mental health among the adult population using social networks.

### Who can participate?

Adults (aged over 18) who use social networks

### What does the study involve?

Recruitment of the participants is voluntary and is made through social media platforms.

Participants are invited to complete a questionnaire. The online questionnaire (created with Google Forms) consists of 31 questions and is accessible on social networks such as Facebook and Twitter.

### What are the possible benefits and risks of participating?

The study does not involve any additional risk in terms of physical and mental health. This study will provide information on the effects of the COVID-19 pandemic on society. Participants do not receive any reward for participating in this research

Where does the study run from?

Grigore T. Popa University of Medicine and Pharmacy (Romania)

When is the study starting and how long is it expected to run for?

November 2020 to December 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Mrs Elena Popa, MD, PhD

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### **Study website**

[https://docs.google.com/forms/d/e/1FAIpQLSehnCNmA5nBR8vN3EBUYarpLBVhAZR3D-9dAqt5u\\_4BuZRghg/viewform](https://docs.google.com/forms/d/e/1FAIpQLSehnCNmA5nBR8vN3EBUYarpLBVhAZR3D-9dAqt5u_4BuZRghg/viewform)

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

U1111-1262-3753

**Secondary identifying numbers**

Nil known

# Study information

## Scientific Title

The effects of the COVID-19 pandemic on mental health: a web-based study among Romanian adults

## Study objectives

The prevalence of anxiety and depression increased in the adult population during the COVID-19 pandemic.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 21/12/2020, Ethics Committee of the Grigore T. Popa University of Medicine and Pharmacy (Universitatea de Medicină și Farmacie "Grigore T. Popa", 6 Universitatii Street, 700115, Iași, România; +40 (0)232 301 603 / +40 (0)232 267 801 / +40 (0)232 267 623; rectorat@umfiasi.ro), ref: 25/21.12.2020

## Study design

Observational cross sectional study

## Primary study design

Observational

## Secondary study design

Cross sectional study

## Study setting(s)

Internet/virtual

## Study type(s)

Screening

## Participant information sheet

No participant information sheet available

## Health condition(s) or problem(s) studied

Anxiety and depression

## Interventions

The researchers are conducting an anonymous cross-sectional web-based survey on anxiety and depression among Romanian adult Internet users. They developed a questionnaire including open-ended and closed questions. The questionnaire includes questions regarding the presence of anxiety or depression.

Recruitment to the study is done on a voluntary basis, and the participants fill in a questionnaire available on a Google drive link. To assess the presence of anxiety and depression, the researchers use two well-recognized and validated tools: the GAP-7 scale for the diagnosis of anxiety and the PHQ-9 scale (nine-item Patient Health Questionnaire) for the diagnosis of

depression. This questionnaire is sent to volunteers in an electronic format through a social network (Facebook, Twitter). As this is a survey study, consent is inferred from the provision of information about participants at the beginning of the survey. All data collected is anonymous and confidential. The study is conducted in accordance with the Helsinki-updated statement. Participants are not remunerated and do not incur any financial costs related to participating in the study.

**Intervention Type**

Other

**Primary outcome measure**

Prevalence of anxiety and depression evaluated using the Patient Health Questionnaire -9 (PHQ-9) scale and the General Anxiety Disorders-7 (GAD-7) scale at a single timepoint

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

29/11/2020

**Completion date**

16/12/2020

**Eligibility****Key inclusion criteria**

Romanian adult Internet users

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

500

**Total final enrolment**

1254

**Key exclusion criteria**

History of mental illness

**Date of first enrolment**

03/12/2020

**Date of final enrolment**

16/12/2020

## Locations

### Countries of recruitment

Romania

### Study participating centre

#### GP Office

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## Sponsor information

### Organisation

Grigore T. Popa University of Medicine and Pharmacy

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### Sponsor type

University/education

### Website

<http://www.umfiasi.ro/Pages/Default.aspx>

### ROR

<https://ror.org/03hd30t45>

## Funder(s)

### Funder type

Other

### Funder Name



Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication of one original paper

### Intention to publish date

03/01/2021

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Miss Teodora Tetia (teodora.tetia@email.umfiasi.ro)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			04/01/2021	No	No
<a href="#">Statistical Analysis Plan</a>			04/01/2021	No	No
<a href="#">Preprint results</a>		30/12/2020	14/01/2022	No	No