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The effects of the COVID-19 pandemic on mental health

Submission date
09/12/2020

Recruitment status
No longer recruiting

Registration date
18/12/2020

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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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Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
U1111-1262-3753

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

Primary study design
Observational

Study design
Observational cross sectional study

Study type(s)
Screening

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(s)
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

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
16/12/2020

Eligibility

Key inclusion criteria
Romanian adult Internet users

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Grigore T. Popa University of Medicine and Pharmacy

ROR
https://ror.org/03hd30t45

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Preprint results		30/12/2020	14/01/2022	No	No
Protocol file			04/01/2021	No	No
Statistical Analysis Plan			04/01/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes