THE EFFECTS OF COVID-19 PANDEMIC ON MENTAL HEALTH

**STUDY PROTOCOL**

1. **Research team**

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| No. | Full name |  Attribute  | Supplementary tasks |
| 1. | ELENA POPA, MD-PhD, Teaching assistant | PrincipalInvestigator | Concept and study design, article writing; corresponding author |
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| 7. | AGNES BACUSCA  | Investigator | Research ethics |
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1. Introduction

On 11 march 2020, WHO declared the novel coronavirus (SARS-CoV2) infection pandemic. (WHO, 2020)

Along with the increased pressure on the medical system, the spread of SARS-Cov2 infection has generated multiple economic and social effects in 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. (Every-Palmer, et al., 2020) (Every-Palmer, et al., 2020).

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 (Pfefferbaum & North, 2020).

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 the methodology for remote evaluation of patients by the family doctor through telephone consultations and / or communication via the Internet.

1. **Aim of the study**: to assess the impact of the Covid-19 pandemic on mental health among the adult population using social networks.
2. **Study design**

The study will be conducted between 30.11.2020 – 31.12.2020.

The steps of the study are:

1. Research methodology development
2. Distribution of questionnaires and data collecting
3. Statistical processing
4. Publication of research results.

Our research will follow the methodology model of a cross-sectional epidemiological study (Wang & Cheng, 2020) conducted online, among adult users of social networks (Facebook, Twitter).

**Study group**

Recruitment of the participants is voluntary and is made through social media platforms. All procedures in this study comply with the ethical standards of the 1964 Helsinki Declaration, revised in 2013 (World Medical Association, 2013), as well as applicable to national legislation. Participants are enrolled in the study after obtaining informed consent online. All data collected is anonymous and confidential.

No criteria for inclusion or exclusion related to ethnicity, race or sex were formulated.

Inclusion criteria:

* Age: over 18 year;
* participation consent.

Exclusion criteria:

* Absence of informed consent
* Preexisting mental disorders.

The online questionnaire (created with Google Forms) consists of 31 questions and is accessible on social networks such as Google and Facebook.(<https://docs.google.com/forms/d/1S1M8EMjRaskkQJxcBp73S6LzeOqvXob0UXsDzy2vtzM/edit?vc=0&c=0&w=1&flr=0>)

The questions to be answered (Annexed to this protocol) include:

1. socio-demographic data (age, sex, environment, education, occupation)

2. alcohol consumption, tobacco during the Covid-19 pandemic

3. status of diagnosis / close contact with SARS-Cov-2

4. pre-existing chronic diseases

5. the presence of anxiety or depression among the interviewed subjects.

To assess the presence of anxiety and depression, we introduced two well-recognized and validated tools in the questionnaire: the GAD-7 scale (General Anxiety Disorders-7) for the diagnosis of anxiety (Spitzer, et al., 2006) and the PHQ-9 scale (Patient Health Questionnaire -9) for the diagnosis of depression (Spitzer, et al., 1999).

The question are formulated in a simple manner and adapted to the GAP-7 and PHQ-9 scale as follows:

*How often have you been bothered by the following* (symptoms related to anxiety or depression) *over the past 2 weeks?*

The answers were adapted according to the points of the scale:

0 – not at all

1 – sometimes

2 – more than half the days

3 – nearly every day.

The data will be stored and statistically processed using IBM SPSS v25.0.

**IV. Premises and discussions:**

At the end of this research, we want to compare the data obtained by us with previous data on the prevalence of anxiety and depression among the adult population in Romania, but also with data reported in studies conducted according to the same methodology in other geographical areas.

For documentation, the databases accessible free of charge by the university teachers on the UMF Iasi-platform https: //login.dbproxy.umfiasi.ro/menu will be used.

1. **Conflicts of interest**: The authors do not declare the existence of conflicts of interest.
2. **Sponsors**: The sponsor of the study is the General Practice Office - Elena Popa, MD, PhD, affiliated teaching assistant at Gr. T. Popa University of Medicine and Pharmacy Iasi, as part of the Family Medicine Discipline from the Department of Preventive Medicine and Interdisciplinarity.

The funding for the study is supported entirely, independently meaning revenue of the GP Office. This research does not receive financial support from other sponsors aside from the mentioned resources.

The access to the scientific literature was made through the databases of the University of Medicine and Pharmacy, to which the sponsor thanks for the support provided.

 The licenses of the programs used in carrying out the study were acquired through the own revenues of the General Practice Office – Dr. ELENA POPA.

1. **Trial registration**: The research will be registered retrospectively on the ISRCTN registry / WHO portal.

Bibliography

Association, W. M., 2013. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA, 310(20), pp. 2191-4.

Every-Palmer, S. et al., 2020. Psychological distress anxiety, family violence, suicidality, and wellbeing în New Zealand during the COVID-19 lockdown: A cross-sectional study.. PLoS One, 15(11), p. e0241658.

Fountoulakis, K. et al., 2020. Self-reported changes în anxiety, depression and suicidality during the COVID-19 lockdown în Greece. J Affect Disord., 2(279), pp. 624-629.

Kelly M., G. J., 2020. În, But Ouţ of Touch: Connecting With Patients During the Virtual Visit. The Annals of Family Medicine, 18(5), pp. 461-462.

Mallen, C., 2020. Research în the time of COVID. EJGP, 26(1), pp. 154-155.

Pfefferbaum, B. & North, C., 2020. Mental Health and the Covid-19 Pandemic.. N Engl J Med, 383(6), pp. 510-2.

Popa, E., Tetia, T. & Coman, A., 2020. Renaissance of family medicine în România during Covid-19. Annals of Family Medicine COVID-19 Collection.

Spitzer, R., Kroenke, K. & Williams, J., 1999. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Paţient Health Questionnaire. JAMA, 282(18), pp. 1737-44.

Spitzer, R., Kroenke, K., Williams, J. & Löwe, B., 2006. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med, 166(10), pp. 1092-7.

Wang, X. & Cheng, Z., 2020. Cross-Sectional Studies:Strengths, Weaknesses, and Recommendations. Chest, 1(158), pp. S65-S71.

WHO, 2020. https://www.who.int/. [Online]

Available at: https://www.who.int/news/item/27-04-2020-who-timeline---covid-19

[Accessed 1 december 2020].

ANNEX 1: Consent – informed agreement

Organizational framework. This research is organized by university teachers affiliated to the Discipline of Family Medicine, within the Department of Preventive Medicine and Interdisciplinarity of the University of Medicine and Pharmacy "Gr. T. Popa” Iasi, Romania

Purpose of the study: You are invited to participate in the study "The effects of the COVID-19 pandemic on mental health". Through this research we aim to highlight the impact of the SARS-CoV-2 pandemic on the mental health of social network users.

Procedures: Participation in the study is purely voluntary (your choice).

 You will be asked to complete once a questionnaire consisting of 31 questions, distributed through the social networks Facebook and Twitter.

Current research does not involve an additional risk to you in terms of physical and mental health.

Benefits. This research will bring information on the effects of the Covid-19 pandemic on society.

Financial considerations. You will not receive any reward for participating in this research (you will not be paid)

Data privacy considerations: All data will be kept confidential. The data collected will not be used for purposes other than research. The use of data will follow the protocol and policies for the protection of anonymity.

The results of this study may be published for scientific purposes, but will not include your name or any personally identifiable information.

Data processing and storage complies with EU Regulation 2016/679 (GDPR).

The medical information resulting from your participation may be made available to the Institution hosting the research, or to other people / institutions if required by law.

You are free to decide whether or not you want to participate in this study. You will not lose any benefit to which you are entitled if you do not accept participation.

INFORMED AGREEMENT

I have read and understood this consent form and agree to participate voluntarily in the study described.

I declare that my rights regarding the protection of personal data have been explained to me according to the national and international regulations in force.