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Protocol of the national representative survey of mental health in the second year after the COVID-19 outbreak: Multilevel analysis of individual and societal factors

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3 **Protocol of the national representative survey of mental health in the second year after**
4 **the COVID-19 outbreak: Multilevel analysis of individual and societal factors**
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29 **Author contributions:**

30 NMB, GK, and LBL designed the study, drafted the protocol, and equally contributed to
31 writing. OT and GK designed the sample. NMB, LBL, GK, LM, ZT, and JT were involved
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36

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Abstract

Introduction. The impact of COVID-19 on mental health (MH) is taking months to become fully apparent. The Serbian national survey - CoV2Soul.RS - was launched to document the MH status of the population concerning the prolonged global public health crisis and to contribute to an international evidence base about prevalence rates during different phases of the pandemic worldwide.

Methods and analysis. The cross-sectional study will collect a representative national sample (18-65 years) by multi-stage probabilistic household sampling method. Trained staff will conduct face-to-face diagnostic interviews (M.I.N.I.). The battery of self-report instruments will be used to measure Quality of Life (QoL), level of distress, and associated protective and harmful psychological and societal factors. We aim to assess prevalence rates of MH disorders and associated QoL, to explore how MH conditions and QoL vary with respect to socio-demographic variables, personality, health status, and traumatic events during pandemics, and to find how these relationships depend on societal factors characterizing municipalities in which our participants live. Moreover, this study will address the perception of pandemic consequences and associated distress in relation to personality and different types of possible mediators. Prevalence rates of MH disorders will be calculated using descriptive statistics. For additional analyses, we will use correlations, analysis of variance, and regression analyses. The hierarchical structure of the data will be explored using Multilevel Random Coefficient Modeling. To investigate the mediation role of relevant variables in the relationships between personality and level of distress Structural Equation Models (SEM) will be used.

Keywords: COVID-19; Stress; Trauma; Prevalence; Mental Health Disorders; Personality; Multilevel Modelling; National Survey, Pandemic

Ethics and dissemination. Ethical Committees of the Faculty of Medicine and Faculty of Philosophy in Belgrade, and Faculty of Philosophy in Novi Sad approved the protocol. Results will be available through reports and placed on the website www.cov2soul.rs and advertised through social media.

Article Summary

Strengths and limitations of this study

- Nationally representative estimates for the prevalence of current mental disorders in otherwise under-researched region of Europe
- Data collection by trained clinicians using a face-to-face state-of-the-art diagnostic instrument
- Identification of protective and harmful psychological and societal factors for MH and QoL during COVID-19 pandemic
- Nested data structure (participants within municipalities) enables thorough exploitation of the data using hierarchical data modeling
- Prolonged duration of pandemic enables evaluation of the full extent of COVID-related MH conditions
- Lack of a reliable baseline national statistics against which it compares the prevalence of mental disorders

Background

Widespread outbreaks of pandemics such as COVID-19 are associated with short- and long-term consequences of psychological and societal distress¹. For instance, the first massive viral infection outbreak in the 21st century – SARS (in 2003), was sometimes regarded as a mental health (MH) catastrophe². Nevertheless, an opposite scenario cannot be ruled out, as some people are becoming more resilient, able to find strengths that lead towards post-traumatic personal growth³. In the COVID-19 pandemic, its burden on health systems, inevitable deterioration of the economy, higher rates of unemployment, global social restrictions, lockdowns, and disturbing media news appear to impose considerable stress on the communities and individuals^{4, 5, 6}. These factors could trigger new-onset MH-disorder or worsen previously stabilized MH-disorders⁷.

In the UK Household Longitudinal Study which was conducted in 2018/2019 and also immediately after the pandemic outbreak, a screening-instrument showed that the prevalence of clinically significant levels of MH disorders increased from approximately 19% to 27%⁸. In the Czech Study which also explored a nationally representative sample at two assessment points (2017 and 2020), the baseline measurements showed the presence of at least one MH disorder in 20% of the sample, followed by an increase to almost 30% within a few months after the COVID-19 outbreak⁷.

The majority of the published studies have been conducted online within the first months of the pandemic, not taking into account progression (or regression) of MH symptoms throughout the pandemic and have mostly relied on diagnostic screening tools or diagnostic questionnaires with a short reference period. Many surveys using convenience sampling and abbreviated measurement strategies have appeared in top-tier journals during the pandemic⁹. However, the overall impact of COVID-19 on MH is taking months to become fully apparent in the general population.

MH status of the population is a multifactorial complex phenomenon, depending on many factors including proximity to the virus (history of CoV2-infection and related exposures), general health status, individual psychological dispositions, traumatic events during pandemics, and multifaceted contextual societal factors. Therefore, conducting a community-based survey to assess the prevalence of psychiatric disorders and to elucidate the key drivers of poor MH using multilevel analyses (Multilevel Random Coefficient Modeling (MRCM))¹⁰ is vital for getting ready to provide pandemic and post-pandemic services that are accessible and timely.

Up till now, only one study of a nationally representative sample used an established psycho-diagnostic instrument to detect MH disorders in relation to the COVID-19 pandemic⁷. However, this report showed the immediate impact of the pandemic outbreak, and its method involved computer-assisted telephone interviewing. To the best of our knowledge, nationally representative field research using structured diagnostic interviews to explore MH status and other MH indices (quality of life – QoL, level of distress) after prolonged exposure to pandemic has not been published yet. Moreover, no one explored all aforementioned factors in relation to societal factors specific to the local municipalities.

The Cov2Soul study and objectives

- To assess prevalence rates of MH disorders and associated QoL in the nationally representative sample, and to identify factors (including socio-demographic data, history of Cov2-infection, Cov-2 distress, and general health status) related to the occurrence of these disorders.

- To explore, using multilevel modeling, how MH conditions and QoL vary with respect to socio-demographic variables, personality, health status, and traumatic events during pandemics, and to find how these relationships depend on societal factors (SF) characterizing municipalities in which they live.
- To explore the perception of pandemic consequences and associated distress in relation to personality, taking into account possible mediators: feelings of loneliness, religious beliefs, and attitude towards COVID-19 conspiracy theories.

Methods

A cross-sectional observational study will include 1200 randomly selected adults aged between 18 and 65 years. Inclusion criteria are: the respondent is eligible for participation in the survey, understands and speaks Serbian fluently, and can give informed consent. Exclusion criteria are: cognitive disability, severe neurological and cognitive impairment leading to a disability to understand items, and deaf and people with impaired hearing with whom research assistants (RAs) cannot communicate verbally.

Setting and participants

The sample will be collected via multi-stage probabilistic household sampling (face-to-face, computer-assisted, or paper-pencil method). The first stage includes a random sampling of municipalities as clusters, while the second stage includes a random sampling of local communities in each municipality. Municipalities and local communities are sampled from four regions (Capital Belgrade and suburbs, Vojvodina, West, and Southeast Serbia) based on the random selection from the database created by the Statistical Office of the Republic of Serbia (database includes information on the name of the settlement, municipality, region, and the number of inhabitants). The third, final stage, deals with the selection of the respondents using a random walk technique. The number of respondents in each start point will not exceed 13, to guarantee that the principle of randomness will not be jeopardized. The number of respondents is proportionate to the size of the community, proportionally to the total sample size. Additionally, the minimum number of respondents sampled from the municipality is 18 (taking into account the municipality size proportionally to the sample size) to allow MRCM.

The sample will include respondents from 137 local communities deployed in 63 municipalities. The number of respondents in local communities ranges between 5 and 13, while at the municipality level it ranges between 18 and 39. In total, the sample will comprise 1200 respondents. This sample size enables detecting the correlation of .10, power of 0.95, alpha level set at 0.05, and the difference in the prevalence of 3% (power of 0.80 at 0.05 level), that might exist between the groups with different CoV2-exposure⁶.

The procedure of data collection

Data will be collected using a standardized Case Report Form (CRF). All instruments except for M.I.N.I. 7.0.2. Standard¹¹ will be collected using an online platform.

Training of Research Assistants (RAs). All RAs will be provided with a comprehensive education to conduct state-of-the-art diagnostic procedures and administration of the test battery. RAs will be MDs and psychologists and will approach potential respondents at their homes. Those willing to participate will give written informed consent. If a respondent is visually impaired or has difficulties reading, RAs will read the items and record the responses of the respondent.

Instruments and measures

Socio-demographic variables include information on age, gender, education, occupation, income, marital status, household size, religiosity, and vaccination status.

The socioeconomic status (SES) will be measured via the social ladder technique¹².

Health status variables assess the overall health status, including somatic and pre-existing psychiatric conditions. The use of anxiolytics and hypnotics will be explored focusing on the period before and during the pandemic, and also in 7 days preceding the assessment.

Prevalence of MH disorders

a) Structured interview to assess the prevalence of 16 most common mental health disorders (MINI 7.0.2 - Standard Adult version). To find the prevalence of serious mental disorders (SMI - Major depressive disorder, Bipolar disorder, or any Psychotic disorder) we will focus on the current and past Depressive, Manic/Hypomanic, or Psychotic episodes. For Post-traumatic stress disorder, Obsessive-compulsive disorder, Social phobia, Panic disorder and Suicidality we will focus on the last month; for Eating disorders on the past 3 months, for Generalized anxiety disorder and Agoraphobia on the past 6 months, while for Alcohol and Substance use disorder the focus will be on the past 12 months. Antisocial personality disorder prevalence is based on the lifetime perspective.

In addition, the following diagnostic groups will be used (in line with the contemporary classifications of psychiatric disorders): (1) Mood disorders (Major depressive episode, Manic episode, and Hypomanic episode); (2) Psychotic disorders; (3) Anxiety disorders (Panic disorder, Agoraphobia, Social phobia, and Generalized anxiety disorder); (4) Obsessive-compulsive disorder; (5) Trauma-related disorders (Post-traumatic stress disorder); (6) Eating disorders, and (7) Substance-related and addictive disorders.

The severity of MH conditions

The suicidality score will be calculated as the sum of the six M.I.N.I. items: Wish for death (weight of 1), Wish for self-harm (weight of 2), Suicidal thoughts (weight of 6), Suicide plan (weight of 10), Suicide attempt in the past 1 month (weight of 10), and Lifetime suicide attempt (weight of 4) (explained in more details by Park et al.¹³). The severity of alcohol and substance use disorder in the past 12 months will be generated by M.I.N.I (mild-moderate-severe). The Patient Health Questionnaire - PHQ-9¹⁴ and the General Anxiety Disorder - GAD-7¹⁵ - depressive and anxiety symptom severity - will be measured with two aforementioned scales, to conclude about the symptom severity and about the current level of distress in all participants. The results will be interpreted as follows: PHQ-9 score 10-14 indicates moderate depression, 15-19 moderate-severe depression, and 20 and above severe depressive symptoms, while GAD-7 score of 10 or more is a cut-point for moderate intensity and 15 or more is representing severe levels of anxiety.

Quality of Life (QoL) will be assessed using the Manchester Short Assessment of Quality of Life (MANSA¹⁶) and a 12-item Short Form Health Survey (SF-12)¹⁷. QoL assumes focusing on satisfaction with life as a whole and with life domains, but also a more precise screening of health status (mental and physical).

Pandemic-related variables

Cov2-exposure consists of the history of Cov2-infection and other Cov2-related situational risks. **History of Cov2-infection** will be classified as none, mild-moderate (infection without ICU admission), and severe (with ICU admission). To assess **Cov-2 related situational risks**, we will use 9 items designed for this study which measure if family members were

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3 diagnosed with COVID-19, if someone from the respondent's family and/or close others died
4 due to COVID-19, did respondent have protective equipment at work, etc.
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7 **List of Threatening Experiences (LTE)**¹⁸ assesses the occurrence of negative life events via
8 12 items. For the present study, the assessment will include events after the pandemic
9 outbreak. The notion of "traumatic events during pandemics" comprises Cov2-exposure and
10 traumatic life events that occurred during the pandemics.
11

12
13 **Covid Stress Scale (CSS)**¹⁹ measures five groups of psychological problems related to the
14 pandemic: 1) fear of contamination by COVID-19; 2) xenophobic fears that foreigners are
15 spreading COVID-19; 3) worry about socioeconomic costs of COVID-19; 4) traumatic stress
16 symptoms associated with direct or indirect exposure to the virus; and 5) COVID-19 related
17 compulsive checking and reassurance seeking.
18

19
20 **Perception of COVID-19 pandemic consequences** on various aspects of life will be
21 measured using 6 items. This scale was created for this research by the authors.
22

23 **Predictor variables**

24 **Basic personality traits.** We will assess six basic personality traits (Honesty, Emotionality,
25 Extraversion, Agreeableness, Conscientiousness, and Openness) using a 60-item HEXACO
26 inventory²⁰. We will also assess a disposition that is proposed by some authors²¹ as the
27 separate personality trait, i.e., Disintegration, a proneness to psychotic-like experiences and
28 behaviors, using a 20-item Delta scale²¹.
29

30 **Mediator variables**

31 **Loneliness** will be assessed using a 3-item scale²².

32 **Conspiracy about the origin of the COVID-19 virus** will be measured using 7 items (6 of
33 them reflecting the most popular conspiracies related to COVID-19 and 1 reverse keyed item
34 articulating the official version of the COVID-19 origin)^{23,24}.
35

36 **Religious beliefs** will be measured by one single question to find how participants appraise
37 themselves.
38

39 **Moderator variables**

40 **Societal factors (SF)** – municipality level contextual variables (such as GDP, level of
41 urbanicity, various demographic characteristics, level of employment, health service
42 availability, numbers of those affected by COVID-19)²⁵.
43
44

45 **Patient and Public Involvement**

46 No patients will be involved in the study. No formal public advisory committee was set up
47 and there was no public involvement in the design and planning of the study. However, our
48 participants will be informed that they can follow everything related to our study via our
49 official website.
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52 **Ethics and dissemination**

53 Ethical Committees of the Faculty of Medicine and Faculty of Philosophy in Belgrade, and
54 Faculty of Philosophy in Novi Sad approved the protocol. Only respondents able to provide
55 informed consent will participate in the study. Respondents can withdraw their consent and
56 withdraw from the study. Respondents will be debriefed. Respondents who have elevated
57 scores on the suicidal ideation subscale will be given a *leaflet* with national SOS phone lines,
58 advising participants to contact their general practitioner/ nearest health care institution.
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3 Collected data will be completely anonymized and used in subsequent analyses at the group
4 level. An anonymized dataset will be uploaded to a repository following all good scientific
5 practices. RAs will be supervised throughout the data collection procedure.
6 Findings will be presented to researchers and clinicians worldwide. A research report based on
7 the study results will be submitted to peer-reviewed journals to be considered for publication.
8 Results will be made available to funders, researchers, policymakers, interested laypeople,
9 through reports placed on the website www.cov2soul.rs, and advertised through social media.
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12 **Protocol and registration**

13 This study is registered with ClinicalTrials.gov (Identifier: NCT04896983).
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16 **Statistical Analysis Plan**

17 Concerning the first objective, we will report descriptive statistics for MH disorders
18 and their relationships with socio-demographic variables (such as gender, age, SES), Cov2-
19 infection, and somatic status. We also plan to investigate how QoL depends on MH status.
20

21 Regarding the second objective, the primary dependent variables will be MH conditions
22 (diagnostic groups and severity of most frequent MH conditions) and QoL. Predictors at level
23 1 will be traumatic events during pandemics, socio-demographic variables, personality traits,
24 and somatic status. Predictors at level 2 will be variables characterizing municipalities where
25 our respondents live. The hierarchical structure of the collected data (level 1 - Individual, and
26 level 2 - SF) will be analyzed using multilevel modeling (MRCM)²⁶. This enables exploration
27 of the moderation effects of SF on the relationships between individual factors (predictors and
28 outcome measures).
29

30 Concerning the third objective, Structural Equation Models (SEM) will be used to
31 investigate the mediator role of loneliness as well as conspiracy and religious beliefs in the
32 relationships between personality and socio-demographic variables, on the one hand, and
33 perception of pandemic consequences and distress, on the other. The other, by-product analyses
34 will be directed toward a better understanding of the latent structures of MH disorders
35 comorbidity, Cov2-distress symptoms, and personality measures, as well as the relationships
36 between MH disorder diagnoses and dimensional structures of symptomatology.
37
38

39 **Strengths and limitations of the study**

40 The project will enable the assessment of MH disorders prevalence in the representative
41 sample of the general population and relate it to pandemic-induced conditions. Moreover, this
42 study aims to understand other psychological and societal factors facilitating/impeding this
43 connection. MH disorders will be assessed in person, using the state-of-the-art diagnostic tool
44 by professionals comprehensively trained and supervised throughout the data-collection
45 process. This enables comparison with other epidemiological studies using the same
46 methodology and will contribute to the international evidence base on the epidemiology of
47 psychiatric disorders.
48

49 Furthermore, the sampling procedure is designed to guarantee the representativeness of
50 the sample for the general population of Serbia. Moreover, the study design (the hierarchical
51 data organization) enables thorough exploration of a unique combination of individual factors
52 (i.e., level 1 variables) and SF (at aggregated, municipal level, i.e., level 2 variables) to
53 understand the MH status of the general population, Cov2-distress, and QoL.
54

55 This is the first epidemiological study of MH conditions using diagnostic interviews in
56 the representative sample of the Serbian general population. Although the comparison with
57 data collected by Priebe and colleagues²⁷ - using the same diagnostic interview on the Serbian
58 population - is planned, the conclusions will be limited given the differences in the sampling
59 procedure. We also acknowledge the possibility that sampling strategy might underestimate
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3 the true prevalence of MH conditions in the population since institutionalized individuals will
4 not be included.

5 Due to a cross-sectional design, it is not possible to unequivocally establish the temporal
6 order of the variables. That is, it could be that personality measurement or reported Cov2-
7 exposure is contaminated by the pandemic-related changes in the MH status.
8
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10 **Impact of the study**

11 Long-term policies are required to meet the MH needs of populations affected by
12 prolonged pandemic conditions and they should target groups with higher risks, which must be
13 identified. Thus, data from this study will be informative for public health institutions whose
14 main areas of activity are analysis, planning, and organization of health care, health promotion,
15 control and disease prevention, and quality of life measurements. The public health sector will
16 be provided with valuable information for further planning of prevention and implementation
17 activities. Finally, the scientific community will benefit from wide dissemination of the
18 previously unavailable national data and with opportunities to include obtained data in
19 forthcoming meta-analytic studies at European and other international levels.
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Mental health in the second year of the COVID-19 pandemic: Protocol for a nationally representative multilevel survey in Serbia

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Mental health in the second year of the COVID-19 pandemic: Protocol for a nationally representative multilevel survey in Serbia

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Author contributions:

NMB, GK, and LBL designed the study, drafted the protocol, and equally contributed to writing. OT and GK designed the sample. NMB, LBL, GK, LM, ZT, and JT were involved with the creation of the test battery. NMB, LM, MPM, and OV designed and conducted RA training and supervision procedures. All authors provided critical feedback on the protocol.

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Abstract

Introduction. The COVID-19 pandemic is likely to have a prolonged impact on mental health (MH); however, the long-term MH effects of the COVID-19 pandemic remain unknown. The Serbian national survey - CoV2Soul.RS - was launched to document the MH status of the Serbian population following the COVID-19 pandemic and to contribute to an international evidence base about MH prevalence rates during different phases of the pandemic.

Methods and analysis. This cross-sectional study was designed to collect a nationally representative sample ($N = 1200$; age 18-65 years; estimated start/end - June/November 2021) using multi-stage probabilistic household sampling. Trained staff will conduct in-person diagnostic interviews. A battery of self-report instruments will be administered to assess the quality of life (QoL), general distress, and associated protective and harmful psychological and societal factors. Analyses will be conducted to delineate the prevalence rates of MH disorders, how MH conditions and QoL vary with respect to socio-demographic variables, personality, health status, and traumatic events during the COVID-19 pandemic, and to test how these relations depend on geographic region. Moreover, this study was designed to explore mechanisms linking personality and the perception of pandemic consequences and associated distress. Prevalence rates of MH disorders will be calculated using descriptive statistics. For additional analyses, we will use correlations, analysis of variance, and regression analyses. The hierarchical structure of the data will be explored using Multilevel Random Coefficient Modeling. Structural equation modeling will be used to investigate the indirect effects of personality on distress through relevant variables.

Keywords: COVID-19; Stress; Trauma; Prevalence; Mental Health Disorders; Personality; Multilevel Modelling; National Survey, Pandemic

Ethics and dissemination. Ethical Committees of the Faculty of Medicine (1322-VII/31) and Faculty of Philosophy in Belgrade (02-33/273), and Faculty of Philosophy in Novi Sad (05-27, br.893/1) approved the protocol. Only respondents able to provide informed consent will participate in the study. Research reports will be submitted to peer-reviewed journals and the results will be placed on the website www.cov2soul.rs to be available to funders, researchers, policymakers, interested laypeople, and will be advertised through social media. ClinicalTrials.gov Identifier: NCT04896983.

Article Summary

Strengths and limitations of this study

- CoV2Soul.RS will enable the assessment of MH disorder prevalence in a representative national adult population in relation to COVID-19.
- Due to the prolonged duration of the COVID-19 pandemic, a more adequate evaluation of the full extent of COVID-related MH conditions is warranted.
- MH disorders will be assessed in person, using a structured diagnostic tool administered by professionals comprehensively trained and supervised to collect data by multi-stage probabilistic household sampling.
- The scientific community will benefit from an opportunity to include obtained data in forthcoming international meta-analytic studies.
- The primary obstacle is the lack of reliable baseline national statistics which limits the possibility to analyze trends in the prevalence of mental disorders prior to and during the COVID-19 pandemic.

Introduction

Viral outbreaks, such as the COVID-19 pandemic, are associated with short- and long-term psychological and societal distress¹. For instance, the first massive viral infection outbreak in the 21st century – SARS (in 2003), resulted in a substantial increase in mental health (MH) symptoms². Alternatively, the prolonged stress associated with living through a pandemic may promote resiliency, as some people can find strengths that lead towards post-traumatic personal growth³. The COVID-19 pandemic has resulted in unprecedented societal burden, from a burden on health systems, inevitable deterioration of the economy, higher rates of unemployment, global social restrictions, lockdowns, and disturbing news stories that impose considerable stress^{4, 5, 6}. These factors could trigger new-onset of MH disorders or worsen previously developed MH disorders⁷.

In the UK Household Longitudinal Study conducted in 2018/2019 and immediately after the pandemic outbreak (2020), a screening instrument showed that the prevalence of clinically significant levels of MH disorders increased from approximately 19% to 27%⁸. In the Czech Study which explored a nationally representative sample at two assessment points (2017 and 2020), the baseline measurements showed the presence of at least one MH disorder in 20% of the sample, whereas the prevalence of at least one MH disorder was 30% within a few months after the COVID-19 outbreak⁷.

The majority of the published studies have been conducted within the first months of the pandemic, not taking into account the progression (or regression) of MH symptoms throughout the pandemic. Further, most studies relied on diagnostic screening tools or diagnostic questionnaires with a short reference period^{9,10}. Indeed, most studies conducted during the COVID-19 pandemic have relied on self-report surveys using convenience sampling and abbreviated measurement strategies¹¹. Due to the overreliance on self-report surveys, the overall impact of COVID-19 on MH is taking months to become fully apparent in the general population.

MH status of the population is a multifactorial complex phenomenon, depending on many factors including proximity to the virus (history of CoV2-infection and related exposures), general health status, individual psychological dispositions, traumatic events during pandemics, and multifaceted contextual societal factors. Therefore, conducting a community-based survey to assess the prevalence of psychiatric disorders and to elucidate the key mechanisms of poor MH using multilevel analyses (Multilevel Random Coefficient Modeling (MRCM))¹² is vital for preparing to provide accessible and timely pandemic and post-pandemic services.

Until now, only one study of a nationally representative sample used an established psychodiagnostic instrument to detect MH disorders following the COVID-19 pandemic⁷. However, this study was conducted close to the onset of the COVID-19 pandemic in the Czech Republic, so the prolonged MH outcomes of the pandemic remain unclear. To the best of our knowledge, nationally representative field research using structured diagnostic interviews to explore MH status and other MH indices (quality of life – QoL, level of distress) after prolonged exposure to pandemic has not been established. Moreover, no one explored all aforementioned factors in relation to societal factors specific to the local municipalities.

The current study was designed to address these gaps in knowledge by: 1) Assessing prevalence rates of MH disorders and associated QoL in a nationally representative Serbian sample, and identifying factors (including socio-demographic data, history of Cov2-infection, Cov-2 distress, and general health status) related to the occurrence of these disorders; 2) Exploring, using multilevel modeling, how MH conditions and QoL vary with respect to socio-demographic variables, personality, health status, and traumatic events during pandemics, and to find how these relationships depend on societal factors (SF) characterizing municipalities in which respondents live, and 3) Exploring the perception of pandemic consequences and

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3 associated distress in relation to personality, taking into account possible mediators: feelings
4 of loneliness, religious beliefs, and attitude towards the COVID-19 conspiracy theories.
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6 7 **Methods and Analysis**

8 A cross-sectional observational study will include 1200 randomly selected adults aged between
9 18 and 65 years. Exclusion criteria will be non-fluent Serbian speakers, severe neurological
10 and cognitive impairment leading to an inability to understand items, and hearing-impaired
11 individuals with whom research assistants (RAs) cannot communicate verbally.
12

13 14 **Setting and Participants**

15 The sample will be collected via multi-stage probabilistic household sampling from June to
16 November 2021. The first stage will include a random sampling of municipalities as clusters,
17 and the second stage will include a random sampling of local communities in each
18 municipality. Municipalities and local communities will be sampled from four regions
19 (Capital Belgrade and suburbs, Vojvodina, West, and Southeast Serbia) based on the random
20 selection from the database created by the Statistical Office of the Republic of Serbia
21 (including information on the name of the settlement, municipality, region, and the number of
22 inhabitants). The third, final stage, will involve the selection of the respondents using a
23 random walk technique performed by RAs. RAs will employ face-to-face interviewing and
24 computer-assisted or paper-pencil method to administer questionnaires. The number of
25 respondents in each start point will not exceed 13, to guarantee that the principle of
26 randomness will not be jeopardized. The number of respondents will be proportionate to the
27 size of the community, proportionally to the total sample size. Additionally, the minimum
28 number of respondents sampled from the municipality is 18 (taking into account the
29 municipality size proportionally to the sample size) to allow MRCM.
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31 The sample will include respondents from 137 local communities deployed in 63
32 municipalities. The number of respondents in local communities ranges between 5 and 13,
33 while at the municipality level it ranges between 18 and 39. A review of the simulation studies
34 showed that higher levels of power were achieved with larger samples at Level 2 than at Level
35 1, and suggested the 30/30 rule of thumb (a minimum of 30 groups with 30 individuals in those
36 groups¹³). Hox¹⁴ proposed the 50/20 rule (i.e., 50 groups with 20 individuals per group). Thus,
37 63 municipalities (Level 2) with 20 individuals per group (Level 1) guarantee adequate power
38 to detect fixed effects, variance components, and cross-level interactions in multi-level
39 modeling.
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41 In total, our sample will comprise 1200 respondents. This sample size enables detecting the
42 correlation of .08, with a power of 0.80, at a .05 alpha level. It means that if only 1% of the
43 variance is shared between mental health variables and COVID-19 exposure indices, the design
44 of our study enables detecting it. Finally, our sample size enables detecting the differences in
45 mental health status (any mental disorder, mood disorders, anxiety disorders, suicidality)
46 between those with history of CoV2-infection (or showing COVID-19 distress) of the size that
47 was reported by the recent Czech study⁷ with the power of .80 or higher, at the .05 alpha level
48 (G*power¹⁵).
49

50 51 52 **Procedure**

53 Data will be collected using a standardized Case Report Form (CRF). All instruments except
54 for M.I.N.I. 7.0.2. Standard¹⁶ will be collected using an online platform.

55 *Training of Research Assistants (RAs)*. All RAs will be provided with a comprehensive
56 education to conduct diagnostic interviews and administer the test battery. RAs will be
57 medical doctors and psychologists and will approach potential respondents at their homes.
58 Those willing to participate will give written informed consent. If a respondent is visually
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impaired or has difficulties reading, RAs will read the items and record the responses of the respondent.

Instruments and measures

Socio-demographic variables include information on age, gender, education, occupation, income, marital status, household size, religiosity, and vaccination status.

The socioeconomic status (SES) will be measured via the social ladder technique¹⁷.

Health status variables assess the overall health status, including somatic and pre-existing psychiatric conditions. The use of anxiolytics and hypnotics will be explored focusing on the period before and during the pandemic, and 7 days preceding the assessment.

Prevalence of MH disorders

a) Structured interview to assess the prevalence of 16 most common mental health disorders (MINI 7.0.2 - Standard Adult version). To find the prevalence of serious mental disorders (SMI - Major depressive disorder, Bipolar disorder, or any Psychotic disorder) we will focus on the current and past Depressive, Manic/Hypomanic, or Psychotic episodes. For Post-traumatic stress disorder, Obsessive-compulsive disorder, Social phobia, Panic disorder, and Suicidality we will focus on the last month; for Eating disorders on the past 3 months, for Generalized anxiety disorder and Agoraphobia on the past 6 months, while for Alcohol and Substance use disorder the focus will be on the past 12 months. Antisocial personality disorder prevalence is based on the lifetime perspective.

In addition, the following diagnostic groups will be used (in line with the contemporary classifications of psychiatric disorders): (1) Mood disorders (Major depressive episode, Manic episode, and Hypomanic episode); (2) Psychotic disorders; (3) Anxiety disorders (Panic disorder, Agoraphobia, Social phobia, and Generalized anxiety disorder); (4) Obsessive-compulsive disorder; (5) Trauma-related disorders (Post-traumatic stress disorder); (6) Eating disorders, and (7) Substance-related and addictive disorders.

MH Symptom Severity

The suicidality score will be calculated as the sum of the six M.I.N.I. items: Wish for death (weight of 1), Wish for self-harm (weight of 2), Suicidal thoughts (weight of 6), Suicide plan (weight of 10), Suicide attempt in the past 1 month (weight of 10), and Lifetime suicide attempt (weight of 4) (explained in more details by Park et al.¹⁸). The severity of alcohol and substance use disorder in the past 12 months will be generated by M.I.N.I (mild-moderate-severe). The Patient Health Questionnaire - PHQ-9¹⁹ and the General Anxiety Disorder - GAD-7²⁰ - depressive and anxiety symptom severity - will be measured with two aforementioned scales, to conclude about the symptom severity and the current level of distress in all participants. The results will be interpreted as follows: PHQ-9 score 10-14 indicates moderate depression, 15-19 moderate-severe depression, and 20 and above severe depressive symptoms, while GAD-7 score of 10 or more is a cut-point for moderate intensity, while 15 or more is representing severe levels of anxiety.

Quality of Life (QoL) will be assessed using the Manchester Short Assessment of Quality of Life (MANSA²¹) and a 12-item Short-Form Health Survey (SF-12)²². QoL assumes focusing on satisfaction with life as a whole and with life domains and more precise screening of health status (mental and physical).

Pandemic-related variables

Cov2-exposure consists of the history of Cov2-infection and other Cov2-related situational risks. **History of Cov2-infection** will be classified as none, mild-moderate (infection without ICU admission), and severe (with ICU admission). To assess **Cov-2 related situational risks**, we will use 9 items designed for this study which measure if family members were

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3 diagnosed with COVID-19 if someone from the respondent's family and/or close others died
4 due to COVID-19, did respondent have protective equipment at work, etc.

5 **List of Threatening Experiences (LTE)**²³ assesses the occurrence of negative life events via
6 12 items. For the present study, the assessment will include events after the pandemic
7 outbreak. The notion of "traumatic events during pandemics" comprises Cov2-exposure and
8 traumatic life events that occurred during the pandemics.

9 **COVID-19 Stress Scale (CSS)**²⁴ measures five groups of psychological problems related to
10 the pandemic: 1) fear of contamination by COVID-19; 2) xenophobic fears that foreigners are
11 spreading COVID-19; 3) worry about socioeconomic costs of COVID-19; 4) traumatic stress
12 symptoms associated with direct or indirect exposure to the virus; and 5) COVID-19 related
13 compulsive checking and reassurance seeking.

14 **Perception of COVID-19 pandemic consequences** on various aspects of life to explore
15 strength and capacity for resumption of normal functioning during and after COVID-related
16 stresses, included different areas of life - family relations, friendships, work/studies, physical
17 activity, financial situation, and internet use. We will ask if these areas of life were affected
18 in positive, neutral, or negative directions (scale 1-5). The scale was created for this study by
19 the authors.

22 **Predictor variables**

23 **Basic personality traits.** We will assess six basic personality traits (Honesty, Emotionality,
24 Extraversion, Agreeableness, Conscientiousness, and Openness) using a 60-item HEXACO
25 inventory²⁵. We will also assess a disposition that is proposed by some authors²¹ as the
26 separate personality trait, i.e., Disintegration, a proneness to psychotic-like experiences and
27 behaviors, using a 20-item Delta scale²⁶.

30 **Mediator variables**

31 **Loneliness** will be assessed using a 3-item scale²⁷.

32 **Conspiracy about the origin of the COVID-19 virus** will be measured using 7 items (6 of
33 them reflecting the most popular conspiracies related to COVID-19 and 1 reverse keyed item
34 articulating the official version of the COVID-19 origin)^{28,29}.

35 **Religious beliefs** will be measured by one single question to find how participants appraise
36 themselves.

39 **Moderator variables**

40 **Societal factors (SF)** – municipality level contextual variables will be assessed (such as
41 GDP, level of urbanicity, various demographic characteristics, level of employment, health
42 service availability, numbers of those affected by COVID-19)³⁰.

43 **Data Analytic Plan**

44 Concerning the first objective, descriptive statistics will be reported for MH disorders and
45 bivariate correlations will be used to present their relations with socio-demographic variables
46 (such as gender, age, SES), Cov2-infection, and somatic status. We also plan to investigate
47 how QoL is associated with MH status.

48 Regarding the second objective, the primary dependent variables will be MH conditions
49 (diagnostic groups and severity of most frequent MH conditions) and QoL. Predictors at level
50 1 will be traumatic events during pandemics, socio-demographic variables, personality traits,
51 and somatic status. Predictors at level 2 will be variables characterizing municipalities where
52 our respondents live. The hierarchical structure of the collected data (level 1 - Individual, and
53 level 2 - SF) will be analyzed using multilevel modeling (MRCM)³¹. This enables exploration
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of the moderation effects of SF on the relationships between individual factors (predictors and outcome measures).

Concerning the third objective, Structural Equation Models (SEMs) will be used to investigate the mediator role of prepandemic indices of MH problems, loneliness, conspiracy, and religious beliefs in the relationships between personality and socio-demographic variables on the one hand, and perception of pandemic consequences and distress on the other.

Patient and Public Involvement

No patients will be involved in the study. No formal public advisory committee was set up and there was no public involvement in the design and planning of the study. However, our participants will be informed that they can follow everything related to our study via our official website.

Ethics and dissemination

Ethical Committees of the Faculty of Medicine (1322-VII/31) and Faculty of Philosophy in Belgrade (02-33/273), and Faculty of Philosophy in Novi Sad approved the protocol (05-27, br.893/1). Only respondents able to provide informed consent will participate in the study. Respondents can withdraw their consent and withdraw from the study. Respondents will be debriefed. Respondents who have elevated scores on the suicidal ideation subscale will be given a *leaflet* with national SOS phone lines, advising participants to contact their general practitioner/ nearest health care institution. Collected data will be completely anonymous. The anonymous dataset will be uploaded to a repository following all good scientific practices. RAs will be supervised throughout the data collection procedure.

Findings will be disseminated worldwide. A research report based on the study results will be submitted to peer-reviewed journals to be considered for publication. Results will be made available to funders, researchers, policymakers, interested laypeople, through reports placed on the website www.cov2soul.rs, and advertised through social media.

Protocol and registration

This study is registered with ClinicalTrials.gov (Identifier: NCT04896983).

Discussion

The project will enable the assessment of MH disorder prevalence in a nationally representative Serbian sample. Moreover, this study was designed to investigate psychological and societal factors serving as mechanisms for worsening MH. MH disorders will be assessed in person, using the state-of-the-art diagnostic tool by professionals familiar with the local context, comprehensively trained, and closely supervised throughout the data-collection process. This will enable comparison to other epidemiological studies using similar methodology and will contribute to the international evidence base on the epidemiology of psychiatric disorders following the COVID-19 pandemic.

Furthermore, the sampling procedure is designed to guarantee the representativeness of the sample for the general population of Serbia. Moreover, the study design (the hierarchical data organization) enables thorough exploration of a unique combination of individual factors (i.e., level 1 variables) and SF (at aggregated, municipal level, i.e., level 2 variables) to understand the MH status of the general population, Cov2-distress, and QoL.

This will be the first epidemiological study to provide nationally representative estimates for the prevalence of MH disorders for community-dwelling adults in Serbia, contributing to the global knowledge on the prevalence of mental disorders for the otherwise under-researched

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3 region of Europe. Although the comparison with data collected by Priebe and colleagues³² -
4 using a similar diagnostic interview on the Serbian population - is planned, the conclusions will
5 be limited given the differences in the sampling procedures (participants in this research were
6 identified in regions that had been directly exposed to war activities).

7
8 We also acknowledge an exceedingly small possibility that sampling strategy might
9 underestimate the true prevalence of MH conditions in the population since institutionalized
10 individuals will not be included. However, there will be no available information about the
11 non-responders, and we will not be able to conclude about this group of people, which could
12 influence our results. Finally, due to a cross-sectional design, it is not possible to unequivocally
13 establish temporal precedence of the variables. That is, it could be that personality
14 measurement or reported Cov2-exposure is influenced by the pandemic-related changes in the
15 MH status.

16
17 Long-term policies are required to meet the MH needs of populations affected by prolonged
18 pandemic conditions and they should target groups with higher risks, which must be identified.
19 Data from this study will be informative for public health institutions whose main areas of
20 activity are analysis, planning, and organization of health care, health promotion, control and
21 disease prevention, and quality of life measurements. The public health sector will be provided
22 with valuable information for further planning of prevention and implementation activities.
23 Finally, the scientific community will benefit from the wide dissemination of the previously
24 unavailable national data and with opportunities to include obtained data in forthcoming meta-
25 analytic studies at European and other international levels.

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Mental health in the second year of the COVID-19 pandemic: protocol for a nationally representative multilevel survey in Serbia

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NMB, GK, and LBL designed the study, drafted the protocol, and equally contributed to writing. OT and GK designed the sample. NMB, LBL, GK, LM, ZT, and JT were involved with the creation of the test battery. NMB, LM, MPM, and OV designed and conducted RA training and supervision procedures. All authors provided critical feedback on the protocol.

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Data availability statement: Technical appendix, statistical code, and dataset will be available from Open Science Framework project page: <https://osf.io/uzct6/>. Survey instruments have been uploaded. Upon data collection, an anonymized data set will be available to interested researchers.

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Abstract

Introduction. The COVID-19 pandemic is likely to have a prolonged impact on mental health (MH); however, the long-term MH effects of the COVID-19 pandemic remain unknown. The Serbian national survey - CoV2Soul.RS - was launched to document the MH status of the Serbian population following the COVID-19 pandemic and to contribute to an international evidence base about MH prevalence rates during different phases of the pandemic.

Methods and analysis. This cross-sectional study was designed to collect a nationally representative sample ($N = 1200$; age 18-65 years; estimated start/end - June/November 2021) using multi-stage probabilistic household sampling. Trained staff will conduct in-person diagnostic interviews. A battery of self-report instruments will be administered to assess the quality of life (QoL), general distress, and associated protective and harmful psychological and societal factors. Analyses will be conducted to delineate the prevalence rates of MH disorders, how MH conditions and QoL vary with respect to socio-demographic variables, personality, health status, and traumatic events during the COVID-19 pandemic, and to test how these relations depend on geographic region. Moreover, this study was designed to explore mechanisms linking personality and the perception of pandemic consequences and associated distress. Prevalence rates of MH disorders will be calculated using descriptive statistics. For additional analyses, we will use correlations, analysis of variance, and regression analyses. The hierarchical structure of the data will be explored using Multilevel Random Coefficient Modeling. Structural equation modeling will be used to investigate the indirect effects of personality on distress through relevant variables.

Ethics and dissemination. Ethical Committees of the Faculty of Medicine (1322-VII/31) and Faculty of Philosophy in Belgrade (02-33/273), and Faculty of Philosophy in Novi Sad (05-27, br.893/1) approved the protocol. Only respondents able to provide informed consent will participate in the study. Research reports will be submitted to peer-reviewed journals and the results will be placed on the website www.cov2soul.rs to be available to funders, researchers, policymakers, and interested laypeople, and will be advertised through social media.

Registration: ClinicalTrials.gov, NCT04896983.

Keywords: COVID-19; Stress; Trauma; Prevalence; Mental Health Disorders; Personality; Multilevel Modelling; National Survey, Pandemic

Strengths and limitations of this study

- CoV2Soul.RS will enable the assessment of MH disorder prevalence in a representative national adult population in relation to COVID-19.
- Due to the prolonged duration of the COVID-19 pandemic, a more adequate evaluation of the full extent of COVID-related MH conditions is warranted.
- MH disorders will be assessed in person, using a structured diagnostic tool administered by professionals comprehensively trained and supervised to collect data by multi-stage probabilistic household sampling.
- The scientific community will benefit from an opportunity to include obtained data in forthcoming international meta-analytic studies.

- The primary limitation is the lack of reliable baseline national statistics which limits the possibility to analyze trends in the prevalence of mental disorders prior to and during the COVID-19 pandemic.

Introduction

Viral outbreaks, such as the COVID-19 pandemic, are associated with short- and long-term psychological and societal distress¹. For instance, the first massive viral infection outbreak in the 21st century – SARS (in 2003), resulted in a substantial increase in mental health (MH) symptoms². Alternatively, the prolonged stress associated with living through a pandemic may promote resiliency, as some people can find strengths that lead towards post-traumatic personal growth³. The COVID-19 pandemic has resulted in unprecedented societal burden, from a burden on health systems, inevitable deterioration of the economy, higher rates of unemployment, global social restrictions, lockdowns, and disturbing news stories that impose considerable stress^{4, 5, 6}. These factors could trigger new-onset of MH disorders or worsen previously developed MH disorders⁷.

In the UK Household Longitudinal Study conducted in 2018/2019 and immediately after the pandemic outbreak (2020), a screening instrument showed that the prevalence of clinically significant levels of MH disorders increased from approximately 19% to 27%⁸. In the Czech Study which explored a nationally representative sample at two assessment points (2017 and 2020), the baseline measurements showed the presence of at least one MH disorder in 20% of the sample, whereas the prevalence of at least one MH disorder was 30% within a few months after the COVID-19 outbreak⁷.

The majority of the published studies have been conducted within the first months of the pandemic, not taking into account the progression (or regression) of MH symptoms throughout the pandemic. Further, most studies relied on diagnostic screening tools or diagnostic questionnaires with a short reference period^{9,10}. Indeed, most studies conducted during the COVID-19 pandemic have relied on self-report surveys using convenience sampling and abbreviated measurement strategies¹¹. Due to the overreliance on self-report surveys, the overall impact of COVID-19 on MH is taking months to become fully apparent in the general population.

MH status of the population is a multifactorial complex phenomenon, depending on many factors including proximity to the virus (history of CoV2-infection and related exposures), general health status, individual psychological dispositions, traumatic events during pandemics, and multifaceted contextual societal factors. Therefore, conducting a community-based survey to assess the prevalence of psychiatric disorders and to elucidate the key mechanisms of poor MH using multilevel analyses (Multilevel Random Coefficient Modeling (MRCM))¹² is vital for preparing to provide accessible and timely pandemic and post-pandemic services. Psychiatrists should alert policy makers and other authorities of the long-term consequences and expected changes in MH service demand¹³. When the pandemic is over it might be that MH services face a shortage of professionals due to burnout and mental exhaustion¹⁴.

Until now, only one study of a nationally representative sample used an established psychodiagnostic instrument to detect MH disorders following the COVID-19 pandemic⁷. However, this study was conducted close to the onset of the COVID-19 pandemic in the Czech Republic, so the prolonged MH outcomes of the pandemic remain unclear. To the best of our knowledge, nationally representative field research using structured diagnostic interviews to explore MH status and other MH indices (quality of life – QoL, level of distress) after prolonged exposure to pandemic has not been established. Moreover, no one explored all aforementioned factors in relation to societal factors specific to the local municipalities.

The current study was designed to address these gaps in knowledge by: 1) Assessing prevalence rates of MH disorders and associated QoL in a nationally representative Serbian sample, and identifying factors (including socio-demographic data, history of Cov2-infection, Cov-2 distress, and general health status) related to the occurrence of these disorders; 2) Exploring, using multilevel modeling, how MH conditions and QoL vary with respect to socio-demographic variables, personality, health status, and traumatic events during pandemics, and to find how these relationships depend on societal factors (SF) characterizing municipalities in which respondents live, and 3) Exploring the perception of pandemic consequences and associated distress in relation to personality, taking into account possible mediators: feelings of loneliness, religious beliefs, and attitude towards the COVID-19 conspiracy theories.

Methods and Analysis

A cross-sectional observational study will include 1200 randomly selected adults aged between 18 and 65 years. Exclusion criteria will be non-fluent Serbian speakers, severe neurological and cognitive impairment leading to an inability to understand items, and hearing-impaired individuals with whom research assistants (RAs) cannot communicate verbally.

Setting and Participants

The sample will be collected via multi-stage probabilistic household sampling from June to November 2021. The first stage will include a random sampling of municipalities as clusters, and the second stage will include a random sampling of local communities in each municipality. Municipalities and local communities will be sampled from four regions (Capital Belgrade and suburbs, Vojvodina, West, and Southeast Serbia) based on the random selection from the database created by the Statistical Office of the Republic of Serbia (including information on the name of the settlement, municipality, region, and the number of inhabitants). The third, final stage, will involve the selection of the respondents using a random walk technique performed by RAs. RAs will employ face-to-face interviewing and computer-assisted or paper-pencil method to administer questionnaires. The number of respondents in each start point will not exceed 13, to guarantee that the principle of randomness will not be jeopardized. The number of respondents will be proportionate to the size of the community, proportionally to the total sample size. Additionally, the minimum number of respondents sampled from the municipality is 18 (taking into account the municipality size proportionally to the sample size) to allow MRCM.

The sample will include respondents from 137 local communities deployed in 63 municipalities. The number of respondents in local communities ranges between 5 and 13, while at the municipality level it ranges between 18 and 39. A review of the simulation studies showed that higher levels of power were achieved with larger samples at Level 2 than at Level 1, and suggested the 30/30 rule of thumb (a minimum of 30 groups with 30 individuals in those groups¹⁵). Hox¹⁶ proposed the 50/20 rule (i.e., 50 groups with 20 individuals per group). Thus, 63 municipalities (Level 2) with 20 individuals per group (Level 1) guarantee adequate power to detect fixed effects, variance components, and cross-level interactions in multi-level modeling.

In total, our sample will comprise 1200 respondents. This sample size enables detecting the correlation of .08, with a power of 0.80, at a .05 alpha level. It means that if only 1% of the variance is shared between mental health variables and COVID-19 exposure indices, the design of our study enables detecting it. Finally, our sample size enables detecting the differences in mental health status (any mental disorder, mood disorders, anxiety disorders, suicidality) between those with history of CoV2-infection (or showing COVID-19 distress) of the size that was reported by the recent Czech study⁷ with the power of .80 or higher, at the .05 alpha level (G^*power^{17}).

Procedures

Data will be collected using a standardized Case Report Form (CRF). All instruments except for M.I.N.I. 7.0.2. Standard¹⁸ will be collected using an online platform.

Training of Research Assistants (RAs). All RAs will be provided with a comprehensive education to conduct diagnostic interviews and administer the test battery. RAs will be medical doctors and psychologists and will approach potential respondents at their homes. Those willing to participate will give written informed consent. If a respondent is visually impaired or has difficulties reading, RAs will read the items and record the responses of the respondent.

Instruments and measures

Socio-demographic variables include information on age, gender, education, occupation, income, marital status, household size, religiosity, and vaccination status.

The socioeconomic status (SES) will be measured via the social ladder technique¹⁹.

Health status variables assess the overall health status, including somatic and pre-existing psychiatric conditions. The use of anxiolytics and hypnotics will be explored focusing on the period before and during the pandemic, and 7 days preceding the assessment.

Prevalence of MH disorders

a) Structured interview to assess the prevalence of 16 most common mental health disorders (MINI 7.0.2 - Standard Adult version). To find the prevalence of serious mental disorders (SMI - Major depressive disorder, Bipolar disorder, or any Psychotic disorder) we will focus on the current and past Depressive, Manic/Hypomanic, or Psychotic episodes. For Post-traumatic stress disorder, Obsessive-compulsive disorder, Social phobia, Panic disorder, and Suicidality we will focus on the last month; for Eating disorders on the past 3 months, for Generalized anxiety disorder and Agoraphobia on the past 6 months, while for Alcohol and Substance use disorder the focus will be on the past 12 months. Antisocial personality disorder prevalence is based on the lifetime perspective.

In addition, the following diagnostic groups will be used (in line with the contemporary classifications of psychiatric disorders): (1) Mood disorders (Major depressive episode, Manic episode, and Hypomanic episode); (2) Psychotic disorders; (3) Anxiety disorders (Panic disorder, Agoraphobia, Social phobia, and Generalized anxiety disorder); (4) Obsessive-compulsive disorder; (5) Trauma-related disorders (Post-traumatic stress disorder); (6) Eating disorders, and (7) Substance-related and addictive disorders.

MH Symptom Severity

The suicidality score will be calculated as the sum of the six M.I.N.I. items: Wish for death (weight of 1), Wish for self-harm (weight of 2), Suicidal thoughts (weight of 6), Suicide plan (weight of 10), Suicide attempt in the past 1 month (weight of 10), and Lifetime suicide attempt (weight of 4) (explained in more details by Park et al.²⁰). The severity of alcohol and substance use disorder in the past 12 months will be generated by M.I.N.I (mild-moderate-severe). The Patient Health Questionnaire - PHQ-9²¹ and the General Anxiety Disorder - GAD-7²² - depressive and anxiety symptom severity - will be measured with two aforementioned scales, to conclude about the symptom severity and the current level of distress in all participants. The results will be interpreted as follows: PHQ-9 score 10-14 indicates moderate depression, 15-19 moderate-severe depression, and 20 and above severe depressive symptoms, while GAD-7 score of 10 or more is a cut-point for moderate intensity, while 15 or more is representing severe levels of anxiety.

Quality of Life (QoL) will be assessed using the Manchester Short Assessment of Quality of Life (MANSA²³) and a 12-item Short-Form Health Survey (SF-12)²⁴. QoL assumes focusing

on satisfaction with life as a whole and with life domains and more precise screening of health status (mental and physical).

Pandemic-related variables

Cov2-exposure consists of the history of Cov2-infection and other Cov2-related situational risks. **History of Cov2-infection** will be classified as none, mild-moderate (infection without ICU admission), and severe (with ICU admission). To assess **Cov-2 related situational risks**, we will use 9 items designed for this study which measure if family members were diagnosed with COVID-19 if someone from the respondent's family and/or close others died due to COVID-19, did respondent have protective equipment at work, etc.

List of Threatening Experiences (LTE)²⁵ assesses the occurrence of negative life events via 12 items. For the present study, the assessment will include events after the pandemic outbreak. The notion of "traumatic events during pandemics" comprises Cov2-exposure and traumatic life events that occurred during the pandemics.

COVID-19 Stress Scale (CSS)²⁶ measures five groups of psychological problems related to the pandemic: 1) fear of contamination by COVID-19; 2) traumatic stress symptoms associated with direct or indirect exposure to the virus; 3) COVID-19 related compulsive checking and reassurance seeking. 4) xenophobic fears that foreigners are spreading COVID-19; 5) worry about socioeconomic costs of COVID-19.

Perception of COVID-19 pandemic consequences on various aspects of life to explore strength and capacity for resumption of normal functioning during and after COVID-related stresses, included different areas of life - family relations, friendships, work/studies, physical activity, financial situation, and internet use. We will ask if these areas of life were affected in positive, neutral, or negative directions (scale 1-5). The scale was created for this study by the authors.

Predictor variables

Basic personality traits. We will assess six basic personality traits (Honesty, Emotionality, Extraversion, Agreeableness, Conscientiousness, and Openness) using a 60-item HEXACO inventory²⁷. We will also assess a disposition that is proposed by some authors as the separate personality trait, i.e., Disintegration, a proneness to psychotic-like experiences and behaviors, using a 20-item Delta scale²⁸.

Mediator variables

Loneliness will be assessed using a 3-item scale²⁹.

Conspiracy about the origin of the COVID-19 virus will be measured using 7 items (6 of them reflecting the most popular conspiracies related to COVID-19 and 1 reverse keyed item articulating the official version of the COVID-19 origin)^{30,31}.

Religious beliefs will be measured by one single question to find how participants appraise themselves.

Moderator variables

Societal factors (SF) – municipality level contextual variables will be assessed (such as GDP, level of urbanicity, various demographic characteristics, level of employment, health service availability, numbers of those affected by COVID-19)³².

Data Analysis Plan

Concerning the first objective, descriptive statistics will be reported for MH disorders and bivariate correlations will be used to present their relations with socio-demographic variables

(such as gender, age, SES), Cov2-infection, and somatic status. We also plan to investigate how QoL is associated with MH status.

Regarding the second objective, the primary dependent variables will be MH conditions (diagnostic groups and severity of most frequent MH conditions) and QoL. Predictors at level 1 will be traumatic events during pandemics, socio-demographic variables, personality traits, and somatic status. Predictors at level 2 will be variables characterizing municipalities where our respondents live. The hierarchical structure of the collected data (level 1 - Individual, and level 2 - SF) will be analyzed using multilevel modeling (MRCM)³³. This enables exploration of the moderation effects of SF on the relationships between individual factors (predictors and outcome measures).

Concerning the third objective, Structural Equation Models (SEMs) will be used to investigate the mediator role of pre-pandemic indices of MH problems, loneliness, conspiracy, and religious beliefs in the relationships between personality and socio-demographic variables on the one hand, and perception of pandemic consequences and distress on the other.

Patient and Public Involvement

No patients will be involved in the study. No formal public advisory committee was set up and there was no public involvement in the design and planning of the study. However, our participants will be informed that they can follow everything related to our study via our official website.

Ethics and dissemination

Ethical Committees of the Faculty of Medicine (1322-VII/31) and Faculty of Philosophy in Belgrade (02-33/273), and Faculty of Philosophy in Novi Sad approved the protocol (05-27, br.893/1). Only respondents able to provide informed consent will participate in the study. Respondents can withdraw their consent and withdraw from the study. Respondents will be debriefed. Respondents who have elevated scores on the suicidal ideation subscale will be given a *leaflet* with national SOS phone lines, advising participants to contact their general practitioner/ nearest health care institution. Collected data will be completely anonymous. The anonymous dataset will be uploaded to a repository following all good scientific practices. RAs will be supervised throughout the data collection procedure.

Findings will be disseminated worldwide. A research report based on the study results will be submitted to peer-reviewed journals to be considered for publication. Results will be made available to funders, researchers, policymakers, interested laypeople, through reports placed on the website www.cov2soul.rs, and advertised through social media.

Registration

This study is registered with ClinicalTrials.gov, NCT04896983.

Discussion

The project will enable the assessment of MH disorder prevalence in a nationally representative Serbian sample. Moreover, this study was designed to investigate psychological and societal factors serving as mechanisms for worsening MH. MH disorders will be assessed in person, using the state-of-the-art diagnostic tool by professionals familiar with the local context, comprehensively trained, and closely supervised throughout the data-collection process. This will enable comparison to other epidemiological studies using similar methodology and will contribute to the international evidence base on the epidemiology of psychiatric disorders following the COVID-19 pandemic.

Furthermore, the sampling procedure is designed to guarantee the representativeness of the sample for the general population of Serbia. Moreover, the study design (the hierarchical data organization) enables thorough exploration of a unique combination of individual factors (i.e., level 1 variables) and SF (at aggregated, municipal level, i.e., level 2 variables) to understand the MH status of the general population, Cov2-distress (including COVID-19 health related anxiety), and QoL.

This will be the first epidemiological study to provide nationally representative estimates for the prevalence of MH disorders for community-dwelling adults in Serbia, contributing to the global knowledge on the prevalence of mental disorders for the otherwise under-researched region of Europe. Although the comparison with data collected by Priebe and colleagues³⁴ - using a similar diagnostic interview on the Serbian population - is planned, the conclusions will be limited given the differences in the sampling procedures (participants in this research were identified in regions that had been directly exposed to war activities).

We also acknowledge an exceedingly small possibility that sampling strategy might underestimate the true prevalence of MH conditions in the population since institutionalized individuals will not be included. However, there will be no available information about the non-responders, and we will not be able to conclude about this group of people, which could influence our results. Also, individuals who have been infected with COVID-19 and have persistent objectively measurable cognitive deficits³⁵, will remain understudied by the present research due to time and financial restraints. Finally, due to a cross-sectional design, it is not possible to unequivocally establish temporal precedence of the variables. That is, it could be that personality measurement or reported Cov2-exposure is influenced by the pandemic-related changes in the MH status.

Long-term policies are required to meet the MH needs of populations affected by prolonged pandemic conditions and they should target groups with higher risks, which must be identified. In particular, limited access to MH care due to unavailability of MH services could negatively impact adequate diagnostic and therapy¹. Present study will be able to provide clinically relevant information about the unmet needs of the population. Data from this study will be informative for public health institutions whose main areas of activity are analysis, planning, and organization of health care, health promotion, control and disease prevention, and quality of life measurements. The public health sector will be provided with valuable information for further planning of prevention and implementation activities. Finally, the scientific community will benefit from the wide dissemination of the previously unavailable national data and with opportunities to include obtained data in forthcoming meta-analytic studies at European and other international levels.

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